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Guidance for the Reregistration of Pesticide Products Containing Fenitrothion as the Active Ingredient

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EPA

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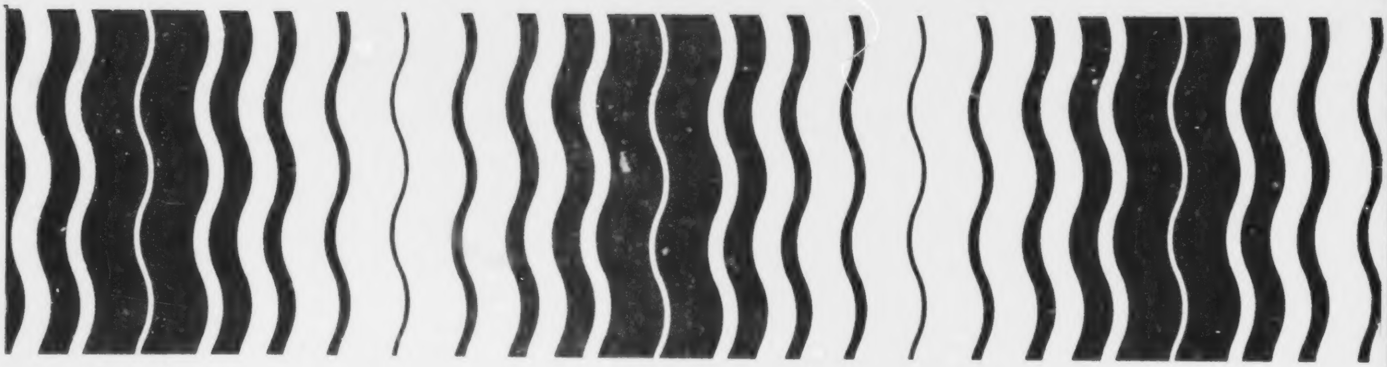

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

FENITROTHION

AS THE ACTIVE INGREDIENT

CAS NO. 122-14-5

EPA CASE NUMBER 445

EPA Pesticide Chemical Code (Shaughnessy)
Number 105901

JULY, 1987

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

TABLE OF CONTENTS

I. Introduction 1

II. Chemical(s) Covered by this Standard 4
  A. Description of Chemical
  B. Use Profile
  C. Regulatory History

III. Agency Assessment 8
  A. Summary
  B. Preliminary Health Risk Assessment
  C. Environmental Profile
  D. Tolerance Reassessment

IV. Regulatory Position and Rationale. 23
  A. Regulatory Positions
  B. Criteria for Registration
  C. Acceptable Ranges and Limits
  D. Required Labeling

V. Products Subject to this Standard 33

VI. Requirement for Submission of Generic Data 35
  A. What are generic data?
  B. Who must submit generic data?
  C. What generic data must be submitted?
  D. How to comply with DCI requirements
  E. Procedures for requesting a change in protocol
  F. Procedures for requesting extensions of time
  G. Existing stocks provisions upon suspension or cancellation

VII. Requirement for Submission of Product-Specific Data . . 41

VIII. Requirement for Submission of Revised Labeling 42

IX. Instructions for Submission. 42
  A. Manufacturing use products (sole active)
  B. Manufacturing use products (multiple active)
  C. End use products
  D. Intrastate products
  E. Addresses

APPENDICES

I. DATA APPENDICES

- Guide to Tables
- Table A
- Table B
- Table C

II. LABELING APPENDICES

- Summary of label requirements and table
- 40 CFR 162.10 Labeling Requirements
- Physical/Chemical Hazards Labeling Statements
- Storage Instructions
- Pesticide Disposal Instructions
- Container Disposal Instructions

III. USE INDEX APPENDIX

IV. BIBLIOGRAPHY APPENDICES

- Guide to Bibliography
- Bibliography

V. FORMS APPENDICES

EPA Form 8580-1	FIFRA §3(c)(2)(B) Summary Sheet
EPA Form 8580-6	Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data
EPA Form 8580-4	Product Specific Data Report
EPA Form 8570-27	Generic Data Exemption Statement

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICAL

The following chemical is covered by this Registration Standard:

Common Name: Fenitrothion

Chemical Name: 0,0-dimethyl 0-(4-nitro-m-tolyl) phosphorothioate

Other Chemical Nomenclature: 0,0-dimethyl 0-(3-methyl-4-nitrophenyl) phosphorothioate; 0,0-dimethyl 0-(4-nitro-m-tolyl) phosphorothioate

Trade Names: Bayer 41831; Bayer S-5660; Bayer S-1102A; AC-47,300; C 47114; Accothion; Cytel; Cyfen; Folithion; Sumithion; Agrothion; Dicofen: Fenstan; Metathion E-50; Verthion; Cekutrothion; Dybar; Fenitox; Novathion; and Nuvanol.

CAS Registry Number: 122-14-5

EPA Pesticide Chemical Code (Shaughnessy) Number: 105901

Empirical Formula: $C_9H_{12}NO_5PS$

Molecular Weight: 277.2

Chemical/Physical Characteristics of a 95% technical grade:
Color: yellow-brownish
Physical state: oily liquid
Odor: data gap
Specific gravity: 1.32 -1.34
Boiling point: 118 °C at 0.01 mm Hg
Melting point: 0.3 °C
Solubility: data gap
pH: data gap
Vapor pressure: data gap
Stability: data gap

B. USE PROFILE

Fenitrothion is a nonsystemic organophosphate insecticide and acaricide federally registered for use on ornamentals; in forests; and in and around domestic, commercial, institutional and industrial areas (including transportation vehicles). End-use formulations consist of a 40% wettable powder; 4 and 8 pound per gallon emulsifiable concentrates (45.5- and 76.8% active ingredient, respectively); and a 93% soluble concentrate/liquid.

There are two forestry uses registered for fenitrothion. In one, fenitrothion, formulated as an emulsifiable concentrate, is applied as a foliar spray to control spuce budworm on spruce and fir tree forests using aerial equipment. The use is limited geographically to the northeastern United States, and application may only be made under the supervision of qualified state or federal officials responsible for insect control programs on forest areas. The second use is for control of southern pine beetles in pine forests using an emulsifiable concentrate formulation. Application is made either by spray application to the bark of trees using hand or power operated ground application equipment; or by a special "hack and squirt" application technique whereby a squirt bottle is used to deliver the insecticide into hack cuts in the tree.

Fenitrothion, formulated as 4 and 8 pound per gallon emulsifiable concentrates, is registered for the control of various household insect pests in and around non-food domestic, commercial, institutional, and industrial areas (including transportation vehicles). Application is made by coarse low pressure spot spray and/or paint brush to infested areas. One product, consisting of a 40% wettable powder, is registered for residual control of adult Anopheline mosquitoes in human dwellings. Application may only be made under the supervision of state or federal officials responsible for malaria control. Fenitrothion is not used in this country for mosquito control; however, the World Health Organization (WHO) recommends its use as a vector control agent for malaria in other countries.

The ornamental use pattern of fenitrothion includes outdoor, greenhouse, and nursery uses. For these uses, fenitrothion, formulated as an emulsifiable concentrate, is applied to the plant as a foliar broadcast or spot spray using ground application equipment.

Technical fenitrothion is manufactured in Japan by the Sumitomo Chemical Company, and is imported into the United States by Sumitomo Chemical America, Inc. The exclusive U.S. distribution rights are currently held by PBI/Gordon Corporation of Kansas City, Missouri. Available usage information for the year 1985 indicates that fenitrothion is used solely on ornamentals, and that the total volume used is relatively small. Usage data further indicate that its use occurs primarily in the North Central and North Eastern portion of the country. Fenitrothion is probably used for control of southern pine beetles in pine forests under the recently approved 24-c "special local need" registrations utilizing the "hack and squirt" method of application, although usage data are not available for confirmation.

The Agency has currently issued 15 registrations to 4 registrants for fenitrothion-containing products. Of this total, two products are formulation intermediates (25.02% and 80%), and one is a technical product (95%). All products are singleactive ingredient formulations[1] with the exception of one product, a formulation intermediate, which contains fenitrothion in combination with d-cis/trans alletrin and MGK 264. For a complete listing of the formulations refer to the EPA Index to Pesticide Chemicals 0,0-dimethyl 0-(4nitro-tolyl) phosphorothioate dated October 31, 1986 (Appendix III). There are 3 "special local need" registrations issued under FIFRA section 24(c) (EPA SLN No.'s MS-860007, LA-860008 and VA-870003). There are no intrastate products containing fenitrothion.

C. REGULATORY HISTORY

The first United States registration for the pesticide fenitrothion was issued by the EPA on March 20, 1975 under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The registration was for control of spruce budworm in forests under the supervision of federal or state officials responsible for insect control programs in forest areas.

Historically, fenitrothion has been used for control of spruce budworm in forests in the northeastern United States, and for household and commercial pest control. These markets have been lost, however, due to problems with bird kills resulting from the forestry use, efficacy, and staining problems resulting from the household and commercial use.

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[1] The Agency considers all currently registered products containing fenitrothion in combination with solvents or diluents to be sole active ingredient formulations. The Agency does not consider solvents or diluents to be insecticidal and therefore, must be declared as inerts.

One Data Call-In has been issued on fenitrothion. The Agency, in 1984, as part of a program to assure the completeness of the chronic toxicology data base of a chemical prior to development of its Registration Standard, required registrants of fenitrothion-containing products to submit a teratology study in a species other than the rat and a chronic feeding study in a non-rodent species. These studies have been received by the Agency. Based on its review, the requirement for a chronic feeding study (non-rodents) has been satisfied; the rabbit teratology study is unacceptable and constitues a new study is required.

III. AGENCY ASSESSMENT

A. SUMMARY

The Agency has reviewed all data currently supporting the registration of fenitrothion. Based on the available data, EPA has reached the following conclusions. The points summarized below are presented in further detail, in the context of EPA's science findings and additional data requirements, in Sections B through D.

1. The Agency is concerned over the potential adverse impact of fenitrothion on birds and aquatic organisms resulting from the forestry use pattern. The Agency is requiring comprehensive aquatic and terrestrial field studies to quantify effects on aquatic and avian species to determine if the hazard indicated by the available field evidence is ecologically significant. The Agency is also requiring restricted-use classification of the forestry uses on an interim basis, pending receipt and evaluation of the required studies. Upon receipt and evaluation of these studies, the Agency will determine whether labeling modification or other regulatory action is warranted.

2. Recent studies, as well as historical data, have implicated fenitrothion along with other organophosphate pesticides in causing human eye effects, such as retinal degeneration and myopia. For these reasons, the Agency is requiring special acute and sub-chronic rat studies to determine fenitrothion's effect on the eye. Upon receipt and evaluation of these studies, the Agency will determine whether labeling modification or other regulatory action is warranted.

3. Technical fenitrothion is a moderately acutely toxic cholinesterase-inhibiting pesticide, which is placed in Toxicity Category II for the oral and dermal route of exposure and Toxicity Category III for the inhalation route of exposure. Technical fenitrothion is mildly irritating to the eyes and skin (Toxicity Category III). Results of a dermal sensitization study using technical fenitrothion were negative. Fenitrothion does not demonstrate acute delayed neurotoxic effects.

4. Because there are substantial chronic toxicology and residue chemistry data gaps for fenitrothion, the Agency will not grant any new food use registrations or new tolerances for fenitrothion until these gaps are filled.

5. Laboratory data show that technical fenitrothion is potentially highly to very highly toxic to birds, honeybees, and aquatic invertebrates. Labeling statements are required by this Standard. Precautions to protect potentially exposed endangered species are required by this Standard and separately through a Pesticide Registration (PR) Notice.

6. The Agency is unable to assess the potential for fenitrothion to contaminate groundwater. Based on preliminary information, fenitrothion degrades fairly rapidly in soil and water, and therefore, may not pose groundwater concerns. However, the environmental fate of fenitrothion is largely uncharacterized, and additional data are needed in order for the Agency to fully assess its fate in the environment and potential for contaminating groundwater.

7. Residue data are not available to determine what levels, if any, of fenitrothion are present in treated homes as a result of application of the 40% wettable powder formulation to control adult Anopheline mosquitoes. The Agency is requiring indoor air residue monitoring data to support this use.

8. The Agency is requiring submission of applicator exposure data from dermal and respiratory routes of exposure to determine whether exposure to applicators during application may be posing health risks.

9. An interim 24 hour reentry interval is imposed for the greenhouse and nursery ornamental uses of fenitrothion, until such time as the appropriate reentry data have been submitted and evaluated.

As a result of this Registration Standard review, the Agency has determined that certain additional or revised label restrictions are necessary. The Agency has also identified missing data necessary to fully evaluate the human and environmental risks associated with the use of fenitrothion as an insecticide/acaricide. These data must be developed in order to maintain registrations of existing products or register any new products containing fenitrothion. A summary of these data gaps is given in Table 1. Please note that this is only a summary and complete details can be obtained by referring to the tables in Appendix I.

The Regulatory Position and Rationale section of this Registration Standard discusses the Agency's position on each of the regulatory issues concerning fenitrothion and the Required Labeling section contains the specific wording required for each of the labeling provisions.

TABLE 1. SUMMARY OF DATA GAPS

(Please refer to the tables in Appendix 1 for detailed information regarding these requirements)

Toxicology

Subchronic oral toxicity--rodent species (for plasma cholinesterase effects)
21-day dermal--rabbit
90-day inhalation--rat
Oncogenicity--mouse
Teratogenicity--rat and rabbit
Reproduction--rat
Mutagenicity--(point mutation assay in mammalian cells, structural chromosomal aberration, and other genotoxic effects)
Metabolism study
Special tests--acute and subchronic tests in rats for eye effects

Environmental Fate/Exposure

Hydrolysis study
Photodegradation in water, soil and air
Aerobic soil metabolism study
Anaerobic aquatic metabolism study
Lab volatility study
Leaching and adsorption/desorption
Soil dissipation study
Forestry dissipation study
Fish accumulation study
Applicator exposure studies
Indoor air residue exposure study
Reentry data

[A field volatility study is reserved pending the results of the lab volatility study; a long-term field dissipation study will not be required if residues reach 50% dissipation prior to the next recommended application; and an aquatic nontarget organisms study is reserved pending the results of the fish accumulation study.]

Fish and Wildlife

Avian reproduction
Actual field testing--birds and aquatic organisms
Acute toxicity to freshwater invertebrates--typical end-use product
Fish early life stage and aquatic invertebrate life cycle
[Pending the results of the environmental fate data and other fish and wildlife tests, a fish life cycle may be required.
Aquatic organism accumulation is reserved pending the results

Table 1. (con't)

of the lower tier tests.]

Plant Testing Requirements

Seed germination/seedling emergence
Vegetative vigor
Aquatic plant growth

Residue Chemistry

Residue analytical methods
Storage stability
Residue data (wheat gluten)

Product Chemistry

All product chemistry studies

B. PRELIMINARY HEALTH RISK ASSESSMENT

Numerous data gaps exist for fenitrothion and few definitive conclusions can be made pending receipt of additional data. The following preliminary health risk assessment is based on the data available.

1. Acute Toxicity

There are adequate acute toxicity studies on file to support registration of technical fenitrothion. Technical fenitrothion is moderately toxic on an acute oral, dermal, and inhalation basis. It falls in Toxicity Category II for oral exposure based on acute oral toxicity values of 800 and 330 mg/kg in female and male rats, respectively. It is in Toxicity Category II for dermal exposure based on acute dermal toxicity values of 1200 and 890 mg/kg in female and male rats, respectively. It is in Toxicity Category III for inhalation exposure based on an acute inhalation toxicity value of 5.0 mg/L in rats. Technical fenitrothion possesses low skin and eye irritation to mammals (Toxicity Category III for both). It has not been shown to be a dermal sensitizer. Acute delayed neurotoxicity studies in the hen showed negative results at dose levels of 500 mg/kg.

2. Subchronic Toxicity

An acceptable subchronic rat oral toxicity has not been submitted to the Agency. The Agency is not making this a requirement, however, since the results from a chronic feeding study in the rat can be translated to this subchronic feeding study. A subchronic oral dog study is also not available, but this study is not needed, since there is an acceptable one year chronic dog study on file with the Agency. Since fenitrothion may be used on sites where significant dermal exposure may be expected to occur, e.g. in greenhouses and domestic dwellings, the Agency is requiring a subchronic dermal toxicity study and a subchronic inhalation study. An acceptable subchronic neurotoxicity study has been submitted to the Agency and shows that fenitrothion does not induce delayed neurotoxicity.

3. Chronic Toxicity and Oncogenicity

Rats and Mice: A No Observable Effect Level (NOEL) for brain and red blood cell cholinesterase of 10 ppm was determined based on a study in which male and female Charles River albino rats were fed dose levels of 10,30, and 100 ppm in the diet for 104 weeks. The test material did not affect the wide variety of parameters examined including appearance, behavior, survival, hematological data, urinalysis, ophthalmology, organ weights, and gross and microscopic examination. Under the conditions of the study, technical fenitrothion inhibited erythrocyte, plasma, and brain cholinesterase activity. The inhibiting action was more pronounced in plasma when compared with erythrocyte and brain activity. A NOEL for plasma cholinesterase was not determined; therefore, a 90-day study is required to determine the NOEL for plasma cholinesterase. No oncogenic effects were noted at the dose levels tested in this study. This study satifies the requirement for a chronic/oncogenicity study in a rodent species.

An oncogenicity study in the mouse showed that fenitrothion is not oncogenic at a concentration of 200 ppm (30.0 mg/kg). However, the Agency has rereviewed this data, and has determined that due to design deficiencies, the study is now considered unacceptable.

Dogs: In a chronic feeding study in which beagle dogs were fed technical fenitrothion at dietary levels of 0, 5, 10 or 50 ppm for 52 weeks, the test material did not affect the wide variety of parameters examined (hematology, clinical chemistry, urinalysis, clinical observations, ophthalmology, body weight, food consumption, organ weights, and mortality). Under the conditions of the study, technical fenitrothion inhibited plasma cholinesterase activity significantly in male and female dogs at the 10 and 50 ppm levels. Red blood cell or brain cholinesterase activities were not affected. In male dogs, there was a mild elevation of blood cholesterol at the highest dose. Histopathology data, recently submitted to the Agency, indicated that the administration of fenitrothion resulted in an increased incidence of abdominal lymph node hemorrhage in 2/6 female dogs at 10 ppm and 2/6 females and 1/6 male dogs at 50 ppm. Abdominal lymph node hemorrhage was not observed in males or females at 5 ppm. The systemic NOEL for this study, based upon inhibition of plasma, is 5 ppm. The Lowest Observable Effect Level (LOEL) is 10 ppm based on plasma cholinesterase activity inhibition.

4. Metabolism

There are no adequate metabolism studies available for technical fenitrothion. Preliminary data indicate that ^{14}C fenitrothion administered to male and female Wistar rats, male and female rabbits, or male beagle dogs, as a single oral dose at 15 mg/kg, was rapidly absorbed and excreted. Excretion of ^{14}C fenitrothion was nearly complete in 48 hours postadministration with approximately 90 and 5 per cent of the excreted dose eliminated in the urine and feces, respectively. Expired air from rats contained no radioactivity and ^{14}C levels in the tissues were not measured. No sex or species related differences in the total excretion were apparent. In rats, a higher single dose (105 mg/kg) or pretreatment with unlabeled fenitrothion for 5 days did not alter the excretion profile. Seventeen metabolites were isolated from the rats, rabbits and dogs, of which eight were identified. The parent compound was not detected in the urine of any animal. In the feces, no metabolites other than those found in the urine were present. This study does not fulfill Agency guideline requirements because the methodology and materials were poorly or incompletely described. The source, age, weight, and number of animals tested were not reported in some instances. Data on the tissue distribution of ^{14}C were inadequate to determine the total recoveries of dose radioactivity. Therefore, a metabolism study (low dose, high dose, and multiple dose) is required to support registration of fenitrothion products.

5. Mutagenicity

The Agency has reviewed the available data on the mutagenicity of fenitrothion and is unable to draw definitive conclusions on its mutagenic potential. Fenitrothion is not considered to be a potential mammalian mutagen, based on an acceptable reverse mutation assay in Salmonella typhimurium. To complete regulatory requirements for mutagenicity testing, the Agency is requiring additional studies; specifically, gene mutation in mammalian cells, structural chromosomal aberrations, and other genotoxic effects, e.g. numerical chromosomal aberrations or direct DNA damage/repair.

6. Teratology

A rat teratology study is required to support registration of fenitrothion products. Based on preliminary data, fenitrothion administered in daily oral doses up to 20 mg/kg to rats during the gestation days 9 to 14 was found to be neither embryotoxic or teratogenic. This study, previously considered as adequate under the Agency's Data Call-In Program for chronic studies, is now considered to be inadequate. The reason for this is that the pregnant rats were treated from days 9-14 of gestation instead of days 6-15 of gestation as called for in the Pesticide Assessment Guidelines Subdivision F. Based upon preliminary data from another teratology study, technical fenitrothion administered in daily oral doses up to 20 mg/kg/day to mice during gestation days 7 to 12 was found also to be neither embyrotoxic or teratogenic. This study is considered to be inadequate for the same reason as given for the rat study.

In response to the Agency's 1984 Data Call-In for fenitrothion, a rabbit (albino) teratology study was submitted in which treatment-related changes in maternal body weight, mortality or behavior were noted. Fetal mortality, number of implantation sites, resorptions, abortions, external development, fetal body weights, viability of young during incubation, internal development or skeletal development were not affected. This study was not considered to be adequate because there were too few litters/dose, inadequate data was submitted, there was no maternal toxicity and there were no historical controls. A new rabbit teratology study was submitted in 1986, and is determined to be unacceptable because semen from more than one strain of rabbit was used to artificially inseminate the does. Due to possible genetic differences in the strains of rabbits used, it is impossible to determine whether fetal effects were due to treatment or parental genetics. Therefore, a new rabbit teratology study is required.

7. Reproduction

A reproduction study is required to support registration of fenitrothion products. Results of preliminary data using technical fenitrothion, in which rats were administered doses of 10, 30, and 150 ppm in the diet through weaning of the first filial generation, and 10, 30, and 100 ppm thereafter, revealed body weight reduction at 150 ppm to the P_1 generation and 100 ppm in the P_2 generation. The lactation index was significantly depressed for the filial generations at the highest dietary levels of fenitrothion. At the 150 and 100 ppm levels, weaning body weights of both sexes of the F_1A, males of the F_1B, and both sexes of the F_2A generations were significantly lower than the control values. This study, previously considered to be adequate under the Agency's Data Call-In Program, is now considered to be inadequate because the study was not performed in accordance with the Pesticide Assessment Guidelines F.

8. Ocular Effects

In Japan, organophosphates have been observed to produce toxic effects to the eye. In the 1950's and 1960's, Japanese workers noted extensive human poisonings by organophosphate pesticides producing a syndrome of effects on vision ranging in severity from myopia, which could be corrected optically, to congestion or degeneration of the optic nerve (it is not known if fenitrothion was one of these pesticides). These myopic effects were later duplicated in experimental studies of organophosphates, including fenitrothion, in dogs. In the fenitrothion study, fenitrothion was administered to dogs for one year at doses of 5 to 50 mg/kg twice weekly, and observed for a year thereafter. Myopia with vertical astigmatism was detected by measuring the shape of the refractive surface of the eye. A reduction in acetylcholinesterase activity was the only additional sign of toxicity. Histopathology revealed a dose-related destruction of the ciliary muscle. In addition, in rat studies using structurally related organophosphates, ethyl parathion, methyl parathion and fenthion, a progression of effects, from functional abnormalities in electrical activity at low acute doses to retinal degeneration at higher doses, were noted.

To confirm the effect of fenitrothion on the eye, the Agency is requiring special acute and subacute rat studies. Upon receipt and evaluation of these data, the Agency will determine whether labeling modification or other regulatory action is warranted.

9. Occupational Exposure Risk

The Agency is unable to fully assess the risk from use of fenitrothion to handlers (mixers, loaders, applicators, etc.) and persons entering treated areas after application. Fenitrothion is a cholinesterase-inhibiting organophosphate pesticide in Toxicity Category II and a possible cause of human occular effects. However, exposure data on fenitrothion are unavailable and surrogate exposure data are inadequate for this purpose. The Agency believes that exposure to handlers of fenitrothion is possible, especially at forest sites during hack-and-squirt application and at greenhouse/nursery ornamental sites during foliar spray application. Exposure to persons performing activities in treated areas of nurseries and greenhouses following application is also possible.

C. ENVIRONMENTAL PROFILE

1. Avian Species

Based on acceptable laboratory data, technical fenitrothion is characterized as highly toxic to upland gamebirds and slightly toxic to waterfowl on an acute oral basis. The single-dose oral toxicity values to bobwhite quail and mallards was determined to be 23.6 mg/kg and 1190 mg/kg, respectively. Based on acceptable subacute dietary studies in birds, technical fenitrothion is characterized as highly toxic to upland gamebirds and slightly toxic to waterfowl, with a subacute toxicity value of 157 ppm for bobwhite quail and 2482 ppm for mallards.

Avian species may be exposed to fenitrothion as a result of its forestry use pattern, e.g. aerial treatment for spruce budworm control and bark application for southern pine bark beetle control. Exposure may occur through direct contact (inhalation and dermal routes), or through ingestion of contaminated foodstuffs (e.g. ingestion of insects by insectivorous birds). Several reports available to the Agency give suggestive evidence that substantial mortalities to upper canopy birds (passerines) may have resulted from operational spraying of fenitrothion in forests to control the spruce budworm. In one report, as many as 2.5 million birds, mainly passerines, may have been killed from 1.8 million hectares of forest treated with fenitrothion. The forest use pattern to control southern pine bark beetle does not have any actual field studies to suggest hazards from this use pattern, although insectivorous birds could be at a high risk.

The observed hazard to birds resulting from spruce budworm control sprayings is not consistent with the results of acceptable laboratory toxicity information. For example, the maximum estimated residue resulting from two treatments at the maximum label rate for spruce budworm control (3 oz. active ingredient per acre per treatment) assuming no degradation or dissipation in the interval between treatments (generally 5 to 7 days) is 75 ppm on foliage. This residue concentration is less than one-half the avian dietary acute toxicity value for bobwhite quail (157 ppm). Residues on insects and seeds, foodstuffs which are most attractive to small passerines, would be less than 20 ppm. Although this information conflicts with the reported bird mortalities, various reasons may account for this phenomenon. For one, the species mostly affected, passerines, may be more susceptible to fenitrothion than are upland gamebirds. Secondly, the birds may have an added pesticide susceptibilty resulting from the dermal and inhalation routes of exposure. Finally, greater exposures could have resulted from misapplication or overlapping spray swaths during treatment.

None of the field studies on aerial operational spraying of fenitrothion in forests are sufficient to allow a definitive assessment of the field effects of fenitrothion to birds. The studies do, however, demonstrate a definite pattern of adverse effects attributable to fenitrothion occuring to birds. The exact magnitude of these impacts cannot be ascertained by the existing data due to the limited scope of the conducted studies and the lack of sufficient detail in the studies concerning methods and results. For this reason, the Agency is requiring a comprehensive field study to quantify effects on avian species to determine if the hazard indicated by the available field evidence is ecologically significant.

2. Aquatic Species

Sufficient information is available to characterize fenitrothion as moderately toxic to both warmwater and coldwater fish, and very highly toxic to aquatic invertebrates. The 96-hour acute toxicity value for brook trout, a coldwater species, is reported to be 1.7 ppm, and the 96-hour acute toxicity value to bluegill, a warmwater species, is reported to be 3.8 ppm. The 96-hour acute toxicity values for freshwater invertebrates is reported to be 3 ppb for the amphipod *Gammarus fasciatus*.

Aquatic organisms may be exposed to fenitrothion from aerial treatment for spruce budworm control and from run-off resulting from bark treatment to control southern pine bark beetles. Direct application to water from a single spruce budworm treatment at the minimum rate (2 oz. a.i. per acre) would result in 92 ppb in 6 inches of water and 15 ppb in 3 ft (1 m) of water. The most sensitive fish (brook trout) has a 96-hour acute toxicity value of 1.7 ppm and the most sensitive aquatic invertebrate (G. fasciatus) has a 96-hour acute toxicity value of 3 ppb. Based on these theoretical calculations, aquatic invertebrates would be expected to be substantially impacted from operational sprayings of fenitrothion. This presumption is supported by several field studies which have reported population reductions in many aquatic invertebrate groups. Based on theoretical calculations, run-off resulting from treatment of fenitrothion for the control of bark beetles can also result in an exposure level greater then 1/2 the aquatic invertebrate acute toxicity value, although actual field data are not available for confirmation.

Additional data are necessary to ascertain the exact magnitude of the impact to aquatic invertebrates. The available evidence is not considered adequate for assessing the magnitude of the observed aquatic fauna losses. For this reason, the Agency is requiring a comprehensive aquatic study to quantify effects on aquatic invertebrate species to determine if the hazard indicated in the available field evidence is ecologically significant and whether the Agency should take additional regulatory action.

3. Restricted-Use Classification

Since the forestry uses of fenitrothion (spruce budworm and southern pine beetle) potentially cause adverse effects on avian and aquatic invertebrate species, the Agency is restricting these uses to certified applicators or persons under their direct supervision on an interim basis pending submittal and evaluation of the required terrestrial and aquatic field studies.

4. Honey Bees

There is sufficient information to characterize fenitrothion as highly toxic to honey bees (acute toxicity value = 0.383 ugs. per bee) when bees are exposed to direct treatment or to dried residues on foliage. Precautionary labeling is required for all fenitrothion products intended for outdoor applications.

5. Effects on Plants

Non-target plant data are required for pesticides with a forestry use pattern. Tier I data on seed germination/seedling emergence, vegetative vigor, and aquatic plant growth are required. No data are available to the Agency to satisfy these requirements.

6. Endangered Species

The Agency has determined that the forestry use pattern of fenitrothion may cause sufficient exposure to pose a direct toxicity hazard to endangered and threatened terrestrial and aquatic species. Labeling which prohibits the use of fenitrothion in the range of endangered and threatened species are required separately through a PR Notice. In addition, the Agency is imposing additional labeling requirements through this Standard, based on a 1981 formal biological opinion received by the Agency from the Office of Endangered Species (OES) in regard to the use of fenitrothion to control southern pine beetles. OES recommended that a statement be included under the use directions warning against the use of fenitrothion within 1/2 mile of red-cockaded woodpecker colonies. OES also recommended against the use in Bastrop and Burleson Counties, Texas without first contacting personnel of the Texas Parks and Wildlife Service in charge of endangered species in order to to protect the Houston toad. These recommendations have been incorporated on product labeling for this use pattern. Formal consultation has been reinitiated with OES to ensure that this recommendation, and the opinion of no jeopardy for sixteen species considered in the consultation, are still valid.

7. Environmental Fate

The Agency is unable to fully assess the environmental fate of fenitrothion because acceptable data are lacking. Preliminary data indicate that fenitrothion degrades fairly rapidly in soil with a half-life of less than a week in non-sterile muck and sandy loam soils. Preliminary data also suggest that fenitrothion is low to intermediately mobile in a variety of soils ranging in texture from sandy loam to clay.

To assess the environmental fate of fenitrothion in conjunction with its forestry and domestic outdoor use pattern, the Agency is requiring the following studies: hydrolysis; photodegradation studies in soil and water; aerobic and anaerobic soil metabolism; aerobic soil and anaerobic aquatic metabolism; leaching and adsorption/desorption; terrestrial field dissipation; forestry dissipation; lab volatility; and fish accumulation. The requirement for a field volatility study is reserved pending the results of the lab volatility study. A long-term field dissipation study will not be required if residues reach 50 percent dissipation prior to the next recommended application. The requirement for an accumulation study in aquatic nontarget organisms is reserved pending the results of the laboratory fish accumulation study.

The potential for groundwater contamination cannot be assessed because acceptable aerobic and anaerobic degradation data and mobility data are lacking. When acceptable environmental fate data are received, the Agency will assess the potential for fenitrothion to contaminate groundwater.

E. TOLERANCE REASSESSMENT

1. Tolerances Issued

There are no domestic uses for fenitrothion on food or feed commodities. There is one established U.S. food additive tolerance which covers residues of fenitrothion in wheat gluten imported from Australia arising from the stored wheat grain treatment registered in that country (2 CFR 193.156[9]). The tolerance level is set at 30 ppm for the combined residues of fenitrothion, fenitrooxon, and p-nitrocresol, of which no more than 15 ppm is fenitrothion or fenitrooxon. In Australia, a 50% EC may be applied to wheat grain to be stored at the rate of 6.6-13.2 milligram of active ingredient per kilogram of grain. Application is to be made at the time of conveyor belt delivery of the grain to bulk storage facilities. Treated grain is to be held in storage and not to be used for processing into food for human consumption or for animal feed, until the fenitrothion residue has decreased to below 10 ppm or until 3 months have elapsed. Codex MRLs (Maximum Residue Limits) for fenitrothion have been established on numerous plant and animal commodities although no U.S. tolerances exist.

2. Residue Data

The residue data reviewed in support of the fenitrothion tolerance for wheat gluten are as follows:

a. The nature of fenitrothion residues in plants is adequately understood based upon available rice metabolism and degradation data. The submitted data indicate that fenitrothion per se (I), desmethyl fenitrothion (IV), and p-nitrocresol (VII) are the major components of the residue in rice grain 0-9 months after postharvest treatment with fenitrothion. Additional metabolites/degradates retaining the aryl phosphate phosphorothioate moiety which are present in very small amounts (i.e., collectively less tha 3% of the total ^{14}C-residue in the grain) were fenitrooxon (II), fenitrothion S-isomer (III), desmethylfenitrooxon (V), and desmethyl fenitrothion S-isomer (VI). Another metabolite/degradate, which does not contain the phosphate moiety but which accounted for up to approximately 7% of the ^{14}C-residue in rice grain was MMNB (IX). No metabolites are considered to be of toxicological significance at this time.

b. Animal metabolism studies are not available for fenitrothion. These studies are not required, since fenitrothion is not federally registered for use on any domestic crops; and therefore residues are not expected to enter the diet of food animals. In the event that future federal registrations for use of fenitrothion on plant commodities used for animal feeds are established, or regulations covering importation of animal products from countries in which fenitrothion is registered for use are established, additional animal metabolism studies may be required.

c. Analytical methodology for determining levels of residues of fenitrothion, fenitrooxon, and p-nitrocresol in plants is adequate for data collection and tolerance enforcement purposes, with the exception that residues of p-nitocresol in or on samples of wheat gluten must be subjected to analysis by multiresidue protocols.

d. Storage stability data are required to support the wheat gluten tolerance. Storage intervals and conditions must be reported from the samples used to generate residue data submitted in support of the tolerance. Data must be provided which depict the decline in residues during the storage intervals and under the conditions reported.

e. Data are inadequate to support the established tolerance for fenitrothion residues in wheat gluten. Data depicting the residues of fenitrothion, fenitooxon, and p-nitrocresol in or on wheat grain held in storage in commercial grain silos for 90 days following an application at the time of the conveyor belt delivery of the 50% EC at 13.2 mg active ingredient of grain, are required. In addition, data depicting whether residues of fenitrothion, fenitrooxon, and p-nitrocresol concentrate in bran, flour, middlings, shorts, and gluten processed from wheat grain bearing measurable weathered residues must be submitted. This information must be accompanied by product labels detailing the use instructions and limitations for fenitrothion on wheat in Australia.

3. Acceptable Daily Intake

A provisional acceptable daily intake (PADI), based on a one-year dog study with a No-Observable Effect Level (NOEL) of 0.125 mg/kg/day, and using a 30-fold safety factor, is calculated to be 0.004 mg/kg/day. A comparision of the published tolerance to the PADI was conducted using the TAS Routine Chronic Analysis. Based on the analysis, a Theoretical Maximum Residue Contribution (TMRC) for the U.S. population was calculated to be 0.000038 mg/kg/day, which utilizes 0.94 per cent of the PADI.

IV. REGULATORY POSITIONS AND RATIONALES

A. SUMMARY OF REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of all available data and other relevant information on fenitrothion the Agency has made the following determinations:

1. No referral to Special Review is being made at this time.

Rationale (fish and wildlife): The Agency is concerned over the potential adverse impact of fenitrothion on birds and aquatic organisms resulting from the forestry use pattern. The Agency has received reports on both bird and aquatic invertebrate kills resulting from aerial spray operations. Terrestrial residue analysis and run-off modeling further indicate that these species could be exposed to potentially hazardous levels of the pesticide. Additional data are needed before the Agency can complete a full assessment of this hazard. For these reasons, the Agency is requiring comprehensive aquatic and terrestrial field studies to determine if the hazard indicated by the available field evidence is ecologically significant. Upon receipt and evaluation of these studies, the Agency will determine if labeling modifications or other regulatory action is warranted.

Rationale (eye effects): Studies available to the Agency have implicated the organophosphates in general, and fenitrothion in particular, in such human eye effects as retinal degeneration and myopia. Because of this concern, the Agency is requiring submission of special rat acute and subchronic studies, such as electroretinograms and direct corneal measurements. These data will provide additional information necessary to confirm the potential for fenitrothion to cause retinal degeneration and changes in corneal shape and structure in the human eye. Pending receipt and evaluation of these studies, the Agency will determine whether labeling modifications or other regulatory action is warranted.

2. All forestry uses of fenitrothon are restricted for use by certified applicators or persons under their direct supervision on an interim basis pending submission and evaluation of the required terrestrial and aquatic field studies.

Rationale: Section 3(d)(1)(C) of the FIFRA provides that some or all uses of a pesticide will be classified for restricted use if the Administrator determines that without such restriction the pesticide "may generally cause unreasonable adverse effects on the environment". For fenitrothion, the Agency has determined that the forestry uses (spruce budworm and southern pine beetle) potentially cause adverse effects on avian and aquatic species. This determination is based upon the bird and aquatic invertebrate kills resulting from aerial spray for spruce budworm control; and terrestrial residue analysis and run-off modeling indicating that these species could be exposed to potentially hazardous levels of the pesticide.

3. The Agency has determined that endangered species label restrictions are necessary to protect endangered and threatened species in forest areas. Through a separate PR Notice 87-4, the Agency is requiring endangered species labeling for all end-use fenitrothion products registered with a forestry use pattern. In addition, the Agency is imposing labeling requirements through this Standard to protect the red-cockaded woodpecker and Houston toad.

Rationale: Fenitrothion is highly toxic to fish and other wildlife. The Agency is limiting the use of fenitrothion in forests where its use has been identified to endanger or jeopardize terrestrial and aquatic species through a separate PR Notice 87-4. In addition, the Agency is imposing additional labeling requirements to protect the Houston toad and red-cockaded woodpecker through this Standard. This is based upon a biological opinion received from the Office of Endangered Species in 1981 regarding the use of fenitrothion to control southern pine beetles in pine forests. OES recommended a statement be included under the directions for use warning against the use of fenitrothion within 1/2 mile of red-cockaded woodpecker colonies, and that a statement be included warning that use in Bastrop and Burleson Counties, Texas should occur only after contacting personnel of the Texas Parks and Wildlife Service or the U.S. Fish and Wildlife Service in charge of endangered species to ensure that adequate safeguards are in place to protect the endangered Houston toad. These recommendations have been incorporated on labeling for this use pattern. The Agency has reinitiated consultation with the Office of Endangered Species (OES), U.S. Department of the Interior to ensure that this recommendation and the opinion of no jeopardy for sixteen species considered in the consultation, are still valid.

4. In order to meet the statutory standard for continued registration, the Agency has determined that fenitrothion products must bear fish and wildlife toxicity warnings.

Rationale: Labeling requirements are imposed since available data indicate that fenitrothion is very highly toxic to

5. The Agency is deferring decisions concerning fenitrothion groundwater contamination until such time as the information required by the Standard have been submitted and reviewed.

Rationale: Groundwater contamination may not be a potential threat because preliminary data indicate rapid degradation of fenitrothion (half-life of 2 to 8 hours in soil). However, the environmental fate of fenitrothion is largely uncharacterized, and additional data are needed in order for the Agency to fully assess its fate in the environment. When these, and other environmental fate data are received and evaluated, the Agency will assess fenitrothion's potential for groundwater contamination.

6. The Agency is requiring special indoor air residue monitoring studies to support fenitrothion's use to control adult Anopheline mosquitoes in human dwellings.

Rationale: Inhalation and dermal exposure to occupants of treated dwellings may occur from use of the 40% wettable powder formulation to control adult Anopheline mosquitoes. The Agency does not have any residue data to support the safety of this use. A special indoor air residue monitoring study is required to support continued use of this product. The study must be designed to evaluate any decline in air residues over time to determine if a reentry time is appropriate.

7. No new tolerances or new food uses will be granted until the Agency has received data sufficient to evaluate the dietary exposure of fenitrothion.

Rationale: Residue chemistry and toxicology data are not sufficient to allow the Agency to assess the existing tolerance for wheat gluten. Residue analytical methods, storage stability data, and residue data are required. The pertinent toxicology data requirements include: mouse oncogenicity, teratology, reproduction, metabolism, and mutagenicity. Until these data are submitted and reviewed, the Agency cannot perform a tolerance reassessment.

8. The Agency is requiring submission of applicator exposure data, and is imposing an interim 24 hour reentry interval for fenitrothion products intended for use on greenhouse and nursery ornamentals pending receipt and evaluation of reentry data. Protective clothing statements as specified in Section IV.D. are required for all products containing fenitrothion.

Rationale: In order to evaluate the risk of occupational exposure to fenitrothion, dermal and respiratory exposure monitoring studies of applicators and reentry protection data are necessary, in addition to the toxicological studies discussed above. Until such studies are submitted and evaluated, interim protection of workers is necessary. Appropriate personal protective equipment during handling of fenitrothion should significantly reduce handler exposure risks. In addition, prohibition of reentry without appropriate personal protective equipment for 24 hours after application to greenhouse and nursery sites should significantly reduce risk to early reentry workers.

9. While data gaps are being filled, currently registered manufacturing-use products (MPs) and end-use products (EPs) containing fenitrothion may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency may elect not to cancel or withhold registration even though data are missing or are inadequate (see FIFRA sections 3(c)(2)(B) and 3(c)(7)). Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.

10. The Agency has identified certain data that will receive priority review when submitted to the Agency.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

§158.135 Toxicology

Special acute and subacute rat tests for ocular effects

§158.130 Environmental Fate

161-1	Hydrolysis
161-2	Photodegradation in water
161-3	Photodegradation on soil
161-4	Photodegradation in air
164-1	Soil dissipation
164-3	Forestry dissipation

165-4	Fish accumulation
	Applicator Exposure Studies
	Indoor air residue monitoring study

§158.140 Reentry Protection

132-1	Foliar Dissipation
133-3	Dermal Exposure
133-4	Inhalation Exposure

§158.145 Wildlife and Aquatic Organisms

71-5	Actual field testing- birds and aquatic organisms
72-4	Fish Early Life Stage and Aquatic Invertebrate Life Cycle

§158.125 Residue Chemistry

All Requirements

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, MPs must contain fenitrothion as the sole active ingredient (solvents or diluents are not considered to be insecticidal, and therefore, must be declared as inerts). Registrants must comply with all terms and conditions described in this section, including submission of an up-to-date Confidential Statement of Formula, submission of revised labeling, commitment to fill data gaps on the schedule specified by the Agency and, when applicable, offer to pay compensation as required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D).

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

Each MP proposed for registration or reregistration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active and intentionally added inert ingredients which are present in the product, as well as impurities found at greater than 0.1 percent.

2. Acute Toxicity Limits

The Agency will consider registration of MPs containing fenitrothion in any Toxicity Category provided the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

All MPs must be labeled for formulation into other manufacturing-use products or into end-use products bearing federally registered uses. Labeling must specify the sites, which are listed in Use Patterns, Appendix III. However, no use may be included on the label where the registrant fails to agree to comply with the data requirement in Table A for that use pattern.

D. REQUIRED LABELING

All MPs and EPs must bear appropriate labeling as specified in 40 CFR 162.10, PR Notices 83-2 and 83-3, and as indicated in this Registration Standard (as appropriate). No EP or MP containing fenitrothion may be released for shipment by a registrant or producer of that product 12 months after the registrant's or producer's receipt of this Registration Standard, unless the product bears an EPA-approved amended label which complies with this Registration Standard.

No EP or MP containing fenitrothion may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person 24 months after issuance of this Registration Standard, unless the product bears an EPA-approved amended label which complies with this Registration Standard.

1. Labeling for MPs

a. The ingredient statement for MPs must declare the active ingredient as:

Fenitrothion: 0,0-dimethyl 0-(4-nitro-m-tolyl) phosphorothioate

b. Labels for MPs must bear the following identifying phrase directly beneath the product name:

"An insecticide for formulating use only."

c. In the directions for use, the following statement must appear:

"Formulators using this product are responsible for obtaining EPA registration of their formulated product."

d. In the directions for use, the following statement regarding acceptable use patterns must appear:

"For formulation into end-use insecticide products intended only for (list acceptable sites)."

NOTE: No use may be included on the label where the registrant fails to agree to comply with the data requirements for that use pattern.

e. If detailed instructions for formulating are not provided on the label, the following statement must appear:

"Refer to attached Technical Bulletin for formulating and other information."

NOTE: The technical bulletin must be submitted with the product label for Agency review.

f. The following fish and wildlife statements are required to appear under the "Environmental Hazards" heading:

"This pesticide is extremely toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

g. The following worker protective clothing statement is required to appear on the label:

"Mixer/loaders must wear goggles or a face shield, chemical-resistant apron, long-sleeved shirt and long pants, or coveralls, and unlined, mid-forearm to elbow length chemical-resistant gloves when mixing, loading, or otherwise handling concentrate."

1. Labeling for EPs

a. The ingredient statement for EPs must declare the active ingredient as:

Fenitrothion: 0,0-dimethyl 0-(4-nitro-m-tolyl)
phosphorothioate

b. The following statement must appear on the front panel of end-use labeling for the forestry uses (spruce budworm and southern pine beetle):

"RESTRICTED USE PESTICIDE
Due to Avian Toxicity and Aquatic
Invertebrate Toxicity

For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification."

c. The wettable powder formulation intended for use as a residual spray in residential dwellings to control adult Anopheline mosquitoes must bear the following statements:

"Remove occupants, pets, birds, and cover fish aquariums before application. Food should be removed and food handling equipment covered during application and/or washed after application is complete. No food handling or preparation areas are to be sprayed. The floor area must be covered before application and the covering disposed of in accordance with disposal procedures specified on this label. After application do not reoccupy until spray deposits have dried. Do not make more than one application every three months. Before reoccupying, open all doors and windows and ventilate thoroughly."

d. All products (except the wettable powder formulation) intended for use indoors must bear the following statements:

"Do not apply this product in edible product areas of food processing plants, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed. Do not use in kitchens or food serving areas while food is exposed. When used in dwellings, avoid deposits which could be frequently contacted by children. Do not permit children or pets in treated areas until surfaces are dry.

e. All products intended for wide area outdoor use, e.g. forestry use, are required to bear the following statement:

"Do not treat areas where food or feed crops are growing. Do not apply to potable water."

f. All products intended for outdoor use for spruce budworm control must bear the following statements:

"This pesticide is toxic to wildlife and extremely toxic to aquatic invertebrates. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes) except under the forest canopy. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area."

g. All products intended for outdoor use (except for spruce budworm control) must bear the following statements:

"This product is toxic to wildlife and extremely toxic to aquatic invertebrates. Do not apply directly to water or wetlands (swamps, marshes, bogs, and potholes). Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area."

h. The following endangered species labeling for fenitrothion products intended for southern pine bark beetle control must also appear on the labeling (in addition to the requirements of the PR Notice 87-4):

"Do not use in Bastrop and Burleson Counties, Texas without first consulting with endangered species personnel of Texas Parks and Wildlife or the U.S. Fish and Wildlife Service (telephone 817-334-2961) to ensure adequate safeguards for the endangered Houston toad. Do not use within 1/2 mile of known red-cockaded woodpecker colonies. Contact the U.S. Fish and Wildlife Service before using this product."

i. The following worker protection statement must appear on all fenitrothion product labels (excluding greenhouse and nursery ornamental use):

"When mixing, loading, spraying or cleaning equipment used to apply this product wear chemical resistant gloves, protective suits or coveralls that cover the arms, legs, and torso, and chemical resistant shoes, boots, or shoe covers. Chemical resistant gloves must be washed with soap and water before removing. All clothing worn during the use of fenitrothion must be laundered separately from household articles. Clothing and protective gear drenched or heavily contaminated with fenitrothion must be destroyed according to state and local regulations. Drenched or heavily contaminated clothing cannot be properly decontaminated. [Aircraft operators: Pilots can wear long-sleeved shirt and long-pants but must have a clean pair of chemical resistant gloves available for exiting the aircraft.]"

j. The following reentry statement and protective clothing statements must appear on all fenitrothion products intended for use on greenhouse and nursery ornamentals:

"Reentry into treated areas is prohibited for 24 hours after the end of the application, unless the protective clothing specified on this label is worn. When mixing, loading, spraying or cleaning equipment, or during early reentry into treated areas, wear chemical resistant gloves, protective suits or coveralls that cover the arms, legs, and torso, and chemical resistant shoes, boots, or shoe covers. Chemical resistant gloves must be washed with soap and water before removing. All clothing worn during the use of fenitrothion must be laundered separately from household articles. Clothing and protective gear drenched or heavily contaminated with fenitrothion must be destroyed according to state and local regulations. Drenched or heavily contaminated clothing cannot be properly decontaminated.

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A and B

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

c. The labeling requirements specified for end use

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission.

The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing the subject pesticide either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

William H. Miller (PM 16)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

APPENDIX I

DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

> Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.
>
> Table B contains product-specific data requirements that apply only to a manufacturing use product.
>
> Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor
N/A = There are no registered use patterns for which the data requirement aplies.

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the receipt date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data be Submitted?	Timeframe for Submission2/
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	TGAI	All			Yes	9 Months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All			Yes	9 Months
61-3 - Discussion of Formation of Impurities	TGAI	All			Yes	9 Months
Analysis and Certification of Product Ingredients:						
62-1 - Preliminary Analysis	TGAI	All			Yes	12 Months
62-2 - Certification of Limits	TGAI	All			Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limits	TGAI	All			Yes	12 Months
Physical and Chemical Characteristics:						
63-2 - Color	TGAI	All			Yes	9 Months
63-3 - Physical State	TGAI	All			Yes	9 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data be Submitted?	Timeframe for Submission2/
§158.120 Product Chemistry (cont'd)						
Physical and Chemical Characteristics: (cont'd)						
63-4 - Odor	TGAI	All			Yes	9 Months
63-5 - Melting Point	TGAI	All			Yes3/	9 Months
63-6 - Boiling Point	TGAI	All			Yes4/	9 Month
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All			Yes	9 Months
63-8 - Solubility	TGAI or PAI	All			Yes	9 Months
63-9 - Vapor Pressure	PAI	All			Yes	9 Months
63-10 - Dissociation Constant	PAI	All			Yes	9 Months
63-11 - Octanol/Water Partition Coefficient	PAI	All			Yes	9 Months
63-12 - pH	TGAI	All			Yes	9 Months
63-13 - Stability	TGAI	All			Yes	15 Months (8 Months - Progress Report)
Other Requirements:						
64-1 - Submittal of Samples	TGAI, PAI	All			Reserved5/	

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data be Submitted?	Timeframe for Submission2/
§158.120 Product Chemistry (cont'd)						

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

3/ Required if the technical is a solid at room temperature.

4/ Required if the technical is a liquid at room temperature.

5/ If samples are needed, the Agency will request them.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission1/
158.125 Residue Chemistry						
171-4 Nature of the Residue (Metabolism)						
Plants	PAIRA	A2/	Yes	00069962 00069963 00113146	No	
Animals	PAIRA	A	Partially	00071860 00150220	Reserved3/	
171-4 Residue Analytical Methods - Plant Residues	TGAI and metabolites	A	Partially	00062928 00113146 00135034	Yes4/	18 Months (8 Months - Progress Report)
171-4 Storage Stability Data	TEP and metabolites	A	Partially	00150219 00150223	Yes5/	18 Months (8 Months - Progress Report)
171-4 Magnitude of the Residue:						
° Wheat Gluten Imported FRom Australia	TEP	A	Partially	00113146 00150224	Yes6/	24 Months7/ (8 Months - Progress Report)

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission1/
§158.125 Residue Chemistry continued:						

1/ Due dates refer to the number of months following receipt of the Registration Standard by the registrant, unless otherwise indicated.

2/ Fenitrothion is not federally registered for use on food or feed commodities in the United States. Data required under §158.125 are required to support the tolerance for wheat gluten imported into this country.

3/ Residues of fenitrothion are not expected to enter the diet of food animals because there are no domestic food uses. If future federal registrations for fenitrothion on plant commodities used for animal feeds, or regulations covering the importation of animal products from countries in which fenitrothion is registered for use become established, additional animal metabolism studies may be required.

4/ Residues of p-nitrocresol in or on samples of wheat gluten must be subjected to analysis by multi-residue protocols. Protocols I-IV are available from the National Technical Information Service in Springfield, VA under Order No. PB 203734/AS. Additional methods, validation data, and residue data may be required in the future if the Agency finds that additional metabolites/degradation products found in plants (grain) constitute residues of toxicological concern.

5/ Storage conditions and intervals must be reported for the samples used to generate the residue data submitted in support of the established tolerance for fenitrothion residues in wheat gluten imported into the U.S. from Australia. Data must also be provided which depict the decline in residues during the storage intervals and under the conditions reported. All residue data must be accompanied by information specifying the storage intervals and conditions for samples analyzed. Data must also be submitted depicting the storage stability of residues of concern in appropriate sample substrates under the storage conditions and time intervals specified. Metabolites other than those covered in the tolerance definition for wheat gluten were found to be significant components of the terminal residue. If these residues are later determined to be of toxicological concern, then storage stability data for these compounds will also be required.

6/ Data depicting residues of fenitrothion, fenitrooxon, and p-nitrocresol in or on wheat grain held in storage in commercial grain silos for 90 days following application at the time of conveyor belt delivery of the 50% EC at 13.2 mg ai/kg of grain are required. Tests must be conducted in a variety of locations under different conditions (including different storage temperatures and humidity) representative of all storage situations encountered in Australia. Data depicting whether residues of fenitrothion, fenitrooxon, and p-nitrocresol concentrate in bran, flour, middlings, shorts, and gluten processed from wheat grain bearing measurable weathered residues are required. Data requirements for bran, flour, middlings, and shorts will be waived if it can be demonstrated that these milled products will not be included in food items or become feed for animals from which foods are obtained and exported from Australia to the United States.

7/ A progress report is due 8 months from receipt of this Standard. Semi-annual reports are due thereafter.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1]/
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	B,F,G,H	No		Yes	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	B,G	No		Yes	9 Months
161-3 - On Soil	TGAI or PAIRA	G	No		Yes	9 Months
161-4 - In Air	TGAI or PAIRA	F	No		Yes	9 Months
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	B,F,G,H	No		Yes	27 Months[2]/ (8 Months - Progress Report)
162-2 - Anaerobic Soil	TGAI or PAIRA	N/A				
162-3 - Anaerobic Aquatic	TGAI or PAIRA	G	No		Yes	27 Months[2]/ (8 Months - Progress Report)
162-4 - Aerobic Aquatic	TGAI or PAIRA	N/A				
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	B,F,G,H	Partially	00126947	Yes[3]/	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1]
§158.130 Environmental Fate (continued)						
163-2 - Volatility (Lab)	TEP	F	No		Yes	12 Months
163-3 - Volatility (Field)	TEP	F	No		Reserved[4]	
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	B,H	No		Yes	27 Months[2] (8 Months - Progress Report)
164-2 - Aquatic (Sediment)	TEP	N/A				
164-3 - Forestry	TEP	G	No		Yes	27 Months[2] (8 Months - Progress Report)
164-4 - Combination and Tank Mixes		N/A				
164-5 - Soil, Long-term	TEP	B,H	No		Reserved[5]	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	N/A				
165-2 - Rotational Crops (Field)	TEP	N/A				
165-3 - Irrigated Crops	TEP	N/A				
165-4 - In Fish	TGAI or PAIRA	B,G	No		Yes	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission1/
§158.130 Environmental Fate (continued)						
165-5 - In Aquatic Nontarget Organisms	TEP	G	No		Reserved6/	
EXPOSURE STUDIES:						
Indoor Air Residue Monitoring	TEP	I	No		Yes7/	12 Months (90 Days- Acceptable Protocol)
Applicators	TEP	B,F,G,H,I	No		Yes	6 Months (90 Days- Acceptable Protocol)

1/ Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

2/ The first progress report is due 8 months after receipt of this Standard. Interim reports are due semi-annually thereafter.

3/ Acceptable data on characterization of pond sediment used in the study MRID 00126947 are required. In addition, a study on the mobility of aged fenitrothion in soil is needed.

4/ Reserved pending the results of the laboratory volatility study.

5/ This study is required if soil residues of fenitrothion and/or its major toxic degradate(s) do not reach 50% dissipation in soil prior to the recommended subsequent application to the same sites utilized in the field dissia

6/ Reserved pending the results of the fish accumulation studies.

7/ An indoor air residue monitoring study to support the use of the 40% WP formulation in human dwellings is required. The study must be designed to evaluate any decline in air residues over time.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1/]
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	B,F	No		Yes	27 Months[2/] (90 Days - Acceptable Protocol) (8 Months - Progress Report)
132-1 - Soil Dissipation	TEP	B,F	No		No[3/]	
133-3 - Dermal Exposure	TEP	B,F	No		Yes	27 Months[2/] (90 days - Acceptable Protocol) (8 Months - Progress Report)
133-4 - Inalation Exposure	TEP	B,F	No		Yes	27 Months[2/] (90 days - Acceptable Protocol) (8 Months - Progress Report)

[1/] Due dates refer to the number of months following receipt of the Standard by the registrant, unless otherwise indicated.

[2/] The first progress report is due 8 months after receipt of this Standard. Interim reports are due semi-annually thereafter.

[3/] Not required because chemical is not applied as a soil application.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1]
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	B,F,G,H,I	Yes	00061091	No	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	B,F,G,H,I	Yes	00071960	No	
81-3 - Acute Inhalation Toxicity - Rat	TGAI	B,F,G,H,I	Yes	00062977	No	
81-7 - Delayed Neurotoxicity - Hen	TGAI	B,F,G,H,I	Yes	00069955	No	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding - Rodent and Nonrodent (Dog)	TGAI	F,H,I	No		Yes[2]	12 Months
82-2 - 21-Day Dermal - Rabbit	TGAI	B,F,G,H,I	No		Yes	9 Months
82-4 - 90-Day Inhalation - Rat	TEP	F,I	No		Yes	15 Months (8 Months - Progress Report)
82-5 - 90-Day Neurotoxicity	TGAI	B,F,G,H,I	Yes	00069955	No	
CHRONIC TESTING:						
83-1 - Chronic Toxicity - Rodent and Nonrodent	TGAI	F,I	Yes	00071965 00143017	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission1/
§158.135 Toxicology (continued)						
83-2 - Oncogenicity - -Rat	TGAI	B,F,G,H,I	Yes	00071965	No	
-Mouse	TGAI	B,F,G,H,I	No		Yes	50 Months3/ (8 Months- Progress Report)
83-3 - Teratogenicity - Rat	TGAI	B,F,G,H,I	No		Yes	15 Months (8 Months- Progress Report)
- Rabbit	TGAI	B,F,G,H,I	No		Yes4/	15 Months (8 Months- Progress Report)
MUTAGENICITY TESTING:						
84-2 - Gene Mutation	TGAI	B,F,G,H,I	Partially	00163432	Yes5/	12 Months (90 Days- Acceptable Protocol)
84-3 - Structural Chromosomal Aberration	TGAI	B,F,G,H,I	No		Yes	12 Months (90 Days- Acceptable Protocol)
84-4 - Other Genotoxic Effects	TGAI	B,F,G,H,I	No		Yes	12 Months (90 Days- Acceptable Protocol)

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1/]
§158.135 Toxicology (continued)						
85-1 - General Metabolism	PAI or PAIRA	B,F,G,H,I	No		Yes	24 Months[3/] (8 Months - Progress Report)
SPECIAL TESTS: Ocular Effects	TGAI	B,F,G,H,I	No		Yes[6/]	9 Months (90 Days- Acceptable Protocol)

1/ Due dates refer to the number of months following receipt of the Registration Standard by the registrant, unless otherwise indicated.

2/ A subchronic rodent study to determine the NOEL for plasma cholinesterase is required. An acceptable 2-year chronic feeding dog study is available and supersedes the need for a subchronic dog study.

3/ The first progress report is due 8 months after receipt of this Standard. Interim reports are due semi-annually thereafter.

4/ The rabbit teratology study submitted by Sumitomo in 1986 is considered to be invalid because semen from more than one strain of rabbit was used to artificially inseminate does. Due to possible genetic differences in the strains of rabbits used, it is impossible to determine whether fetal effects were due to the treatment or parental genetics.

5/ A point mutation assay in mammalian cells is required.

6/ An acute toxicity test in the rat is required in which cholinesterase activity (blood) and retinal activity (electroretinography) are measured. For the acute test, the Agency recommends a study design which includes acute sublethal doses, tests performed pretest, at 4 days, and repeated at intervals until full recovery. Measurements must include cholinesterase activity (blood) and retinal electrical activity (eletroretinography). For the subchronic rat study (which should be combined with other subchronic oral requirements), the Agency recommends a study design which includes 3 orally treated groups and 1 control group. Observations should be made pre-test and at intervals for at least 90 days; the doses should be based on the results of the acute study and previously submitted chronic study. Measurements must include cholinesterase activity (blood), retinal electrical activity (electroretinography), ophthalmoscopic observations, fundus observations/photographs, clinical observations of potential cholinergic signs, body weights, and histopathology of the eye (light and EM, including intra- and extraocular muscle, optic nerve and retina). An acceptable protocol must be submitted within 90 days of receipt of this Standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1]/
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING:						
71-1 - Acute Avian Oral Toxicity	TGAI	B,F,G,H	Yes	00160000 00126885 00126886	No	
71-2 - Avian Subacute Dietary						
- Upland Game Bird	TGAI	B,F,G,H	Yes	00022923	No	
- Waterfowl	TGAI	B,F,G,H	Yes	00022923	No	
71-3 - Wild Mammal Toxicity	TGAI	N/A				
71-4 - Avian Reproduction Upland Game Bird and Waterfowl	TGAI	G	Partially	00159565	Yes[2]/	24 Months[4]/ (90 Days-Acceptable Protocol)
71-5 - Simulated Field Testing and Actual Field Testing - Mammals and Birds	TEP	G	Partially	00126929 00126919 00126920 00093939 40243801	Yes[3]/	48 Months[4]/ (terrestrial field study) (90 Days-Acceptable Protocol) 24 Months[4]/ (screening study) (90 Days-Acceptable Protocol)

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1]/
§158.145 Wildlife and Aquatic Organisms (continued)						
72-1 - Freshwater Fish Toxicity						
- Coldwater Fish Species	TGAI	B,F,G,H	Yes	40094602 00125909 00120401	No	
	TEP	G	Yes	40094602 00125909 00120401	No	
- Warmwater Fish Species	TGAI	B,F,G,H	Yes	40094602	No	
	TEP	G	Yes	40094602 00128048	No	
AQUATIC ORGANISM TESTING:						
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	B,F,G,H	Yes	40094602 00125909 00120401	No	
- Unique Formulation	TEP	G	No		Yes	9 Months
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI	G	Partially	40228401	No[5]/	
72-4 - Fish Early Life Stage, and - Aquatic Invertebrate Life Cycle	TGAI	G	No		Yes[6]/	15 Months (8 Months- Progress Report)

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms (continued)						
72-5 - Fish - Life Cycle	TGAI	G	No		Reserved7/	
72-6 - Aquatic Organism Accumulation	TGAI,PAI or Degradation Product	G	No		Reserved7/	
72-7 - Simulated Field Testing and Actual Field Testing - Aquatic Organisms	TEP	G	Partially	0093942 0126915 0093940 0126916 0126958 0126956	Yes8/	48 Months4/ (aquatic field study) (90 Days-Acceptable Protocol) 24 Months4/ (screening study) (90 Days-Acceptable Protocol)

1/ Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

2/ Required for forest uses which allow repeat applications. The submitted studies (0159665,0015966) did not specify the percent active ingredient of the test material.

3/ The hazard assessment for the forest uses indicate a risk to birds. A comprehensive terrestrial field study is needed to quantify effects on avian populations for the spruce budworm use to determine if the hazard indicated by available field evidence is ecologically significant. A screening terrestrial field study is needed for the pine bark beetle uses to determine if the hazard indicated by the available laboratory and exposure information will result in significant adverse effects to birds or other vertebrates (e.g. reptiles and amphibians). Acceptable protocols are due 90 days from receipt of this Standard. A document is available from the Agency which outlines an acceptable approach to these studies.

4/ A progress report is due 8 months from receipt of this Standard. Semi-annual reports are due thereafter.

5/ The submitted data do not fulfill guideline requirements; but the forestry uses of fenitrothion do not require marine/estuarine testing.

6/ Data reviewed under this Standard indicate a need for chronic data for both freshwater fish and aquatic invertebrate; e.g. the Estimated Environmental Concentration (EEC) exceeds 0.01 of the LC_{50}'s for both fish and aquatic invertebrates.

7/ Reserved pending receipt of lower tier tests and environmental fate studies.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms (continued)						

8/ Hazard assessment of the forest uses (spruce budworm and pine bark beetle) indicates a risk to aquatic organisms. A comprehensive aquatic field study to quantify effects on aquatic organisms is needed for the spruce budworm uses to determine if the hazard indicated by available field evidence is ecologically significant. A screening field study to qualify exposure and mortality to aquatic organisms is needed for the pine bark beetle uses to determine if the hazard indicated by available laboratory and exposure information will result in significant adverse effects to aquatic organisms.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission 1/
§158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey Bee Acute Contact LD_{50}	TGAI	B,H	Yes	00036935 05001991	No	
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	B,H	Yes	00126931	No	
141-4 - Honey Bee Subacute Feeding Study	Reserved2/					
141-5 - Field Testing for Pollinators	TEP	B,H	No		No3/	
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute Toxicity to Aquatic Insects	Reserved4/					
142-2 - Aquatic Insect Life Cycle Study	Reserved4/					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	Reserved4/					
143-1 thru 143-3 - NONTARGET INSECT TESTING-PREDATORS AND PARASITES	Reserved4/					

1/ Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

2/ Reserved pending development of test methodology.

3/ This requirement is imposed on a case-by-case basis. Data reviewed under this Standard do not indicate a need for a field study.

4/ Reserved pending Agency decision as to whether data requirement should be established.

TABLE A

GENERIC DATA REQUIREMENTS FOR FENITROTHION

Data Requirement		Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission 1/
121-1	Target Area Phytotoxicity	TEP	G	No		No[2]	
122-1	TIER I Seed Germination/ Seedling Emergency	TGAI	G	No		Yes	9 Months
122-1	Vegetative Vigor	TGAI	G	No		Yes	9 Months
122-2	Aquatic Plant Growth	TGAI	G	No		Yes	9 Months
123-1	TIER II Seed Germination/ Seedling Emergency	TGAI	G	No		Reserved[3]	
123-1	Vegetative Vigor	TGAI	G	No		Reserved[3]	
123-2	Aquatic Plant Growth	TGAI	G	No		Reserved[3]	
124-1	TIER III Terrestrial Field	TEP	G	No		Reserved[3]	
124-2	Aquatic Field	TEP	G	No		Reserved[3]	

1/ Due dates refer to the number f months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

2/ Data are only required for Special Review and certain other public health situations.

3/ Reserved pending the results of lower tier tests.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENITROTHION

Data Requirement	Test2/ Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation 1/	Must Additional Data be Submitted?	Timeframe for Submission3/
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	All			Yes	9 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All			Yes	9 Months
61-3 - Discussion of Formation of Impurities	MP	All			Yes	9 Months
Analysis and Certification of Product Ingredients:						
62-1 - Preliminary Analysis	MP	All			Yes	12 Months
62-2 - Certification of Limits	MP	All			Yes	12 Months
62-3- Analytical Methods to Verify Certified Limit	MP	All			Yes	12 Months
Physical And Chemical Characteristics:						
63-2 - Color	MP	All			Yes	9 Months
63-3 - Physical State	MP	All			Yes	9 Months
63-4 - Odor	MP	All			Yes	9 Months

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENITROTHION

Data Requirement	Test Substance[1]/	Use Patterns	Does EPA Have Data?[2]/	Bibliographic Citation [2]/	Must Additional Data be Submitted?	Timeframe for Submission[3]/
§158.120 Product Chemistry (continued)						
Physical and Chemical Characteristics (continued)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	All			Yes	9 Months
63-12 - pH	MP	All			Yes	9 Months
63-14 - Oxidizing or Reducing Action	MP	All			Yes	9 Months
63-15 - Flammability	MP	All			Yes	9 Months
63-16 - Explodability	MP	All			Yes	9 Months
63-17 - Storage Stability	MP	All			Yes	15 Months (8 Months - Progress Report)
63-18 - Viscosity	MP	All			Yes	9 Months
63-19 - Miscibility	MP	All			Yes	9 Months
63-20 - Corrosion Characteristics	MP	All			Yes	9 Months
Other Requirements:						
64-1 - Submittal of Samples	MP	All			Reserved[4]/	

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENITROTHION

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data[2]	Bibliographic Citation[2]	Must Additional Data be Submitted?	Timeframe for Submission[3]
§158.120 Product Chemistry (continued)						

[1] Formulation intermediates are also included in the category of manufacturing-use products.

[2] Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing-use product. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

[3] Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

[4] If samples are needed, the Agency will request them.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENITROTHION

Data Requirement	Test[1/] Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[2/]
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	MP	All	Partially	00061091	Yes[3/]	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP	All	Partially	00071960	Yes[3/]	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	All	Partially	00062977	Yes[3/]	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	All	Partially	00062976	Yes[3/]	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	All	Partially	00062976	Yes[3/]	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	All	Partially	00061091	Yes[3/]	9 Months

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[1/] Formulation intermediates are also included in the category of manufacturing-use products.

[2/] Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

[3/] Data will support technical grade formulations (97% and above). Data must be submitted to support all other formulations.

APPENDIX IV

BIBLIOGRAPHY APPENDICES

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

    (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

    (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

    (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

    (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Fenitrothion Standard

MRID	CITATION
00022923	Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds: Special Scientific Report--Wildlife No. 191. (U.S. Dept. of the Interior, Fish and Wildlife Service, Patuxent Wildlife Research Center; unpublished report)
00036935	Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By University of California, Dept. of Entomology. ?: UC, Cooperative Extension. (Leaflet 2287; published study.)
00061091	Miyamoto, J.; Kadota, T. (1972) Toxicological Studies with Sumithion. (Unpublished study received on unknown date under unknown admin. no.; submitted by Sumitomo Chemical Co., Ltd., Baltimore, Md.; CDL:127719-B)
00062928	Patchett, G.G. (1976) Determination of Residues of Sumithion and Sumioxon in Crops and Soil. Method no. RRC 76-50 dated Nov 23, 1976. (Unpublished study received Dec 8, 1980 under 476-EX-100; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL: 243935-E)
00062976	Saunders, D.R. (1978) Toxicity Evaluation: Sumithion 8E: Toxicology Laboratory Report: T-6290. (Unpublished study received Dec 8, 1980 under 476-EX-100; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:243934-A)
00062977	Leong, B.K.J. (1978) Acute Inhalation Toxicity Study in Rats: IRDC No. 153-080. (Unpublished study received Dec 8, 1980 under 476-EX-100; prepared by International Research and Development Corp., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:243934-B)
00069955	Miyamoto, J.; Kadota, T.; Kagoshima, M. (1976) Acute Oral Toxicity and Delayed Neurotoxicity of Sumithion in Hens. Rev. (Unpublished study, including letter dated Aug 26, 1976 from N. Ito to J. Miyamoto, received Feb 28, 1978 under 476-EX-80; prepared by Sumitomo Chemical Co., Ltd., Japan, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:096826-D)
00069962	Hosokawa, S.; Miyamoto, J. (1974) Metabolism of 14C-labelled Sumithion, O,O-dimethyl O-(3-methyl-4-nitrophenyl) phosphorothioate in apples. Botyu-Kagaku 39(II):49-53. (Also in unpublished submission received Feb 28, 1978 under 476-EX-80; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL: 096826-L)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Fenitrothion Standard

MRID CITATION

00120401 Woodward, D.; Mauck, W. (1980) Toxicity of five forest insecticides to cutthroat trout and two species of aquatic invertebrates. Bull. Environm. Contam. Toxicol. 25:846-854. (Submitter 69597; also in unpublished submission received Dec 9, 1982 under 3125-327; submitted by Mobay Chemical Corp., Kansas City, MO; CDL: 248989-0)

00125909 Schoettger, R.; Mauck, W. (1976) Toxicity of Experimental Forest Insecticides to Fish and Aquatic Invertebrates: Submitter 63089. (Unpublished study received Jun 26, 1978 under 3125-EX-150; prepared by U.S. Fish & Wildlife Service, Fish-Pesticide Research Laboratory, submitted by Mobay Chemical Corp., Kansas City, MO; CDL:234509-T)

00126885 Fletcher, D. (1971) Report to ...: Acute Oral Toxicity Study with Sumithion in Ringneck Pheasants: IBT No. J9993. (Unpublished study received Mar 15, 1973 under 10308-2; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Sumitomo Chemical Co., Ltd., Baltimore, MD; CDL:004891-B)

00126886 Fletcher, D. (1971) Report to ...: Acute Oral Toxicity Study with Sumithion Technical in Mallard Ducks: IBT No. J9992. (Unpublished study received Mar 15, 1973 under 10308-2; prepared by Industrial Bio-Test Laboratoeies, Inc., submitted by Sumitomo Chemical Co., Ltd., Baltimore, MD; CDL:004891-C)

00126915 Vincent, F. (1969) Observations of the Effects of Sumithion on Aquatic Farms: Spruce Budworm Control Project, Maine. (Unpublished study received Mar 15, 1973 under 10308-2; submitted by Sumitomo Chemical Co., Ltd., Baltimore, MD; CDL:004892-T)

00126916 Dimond, J.; Malcolm, S. (1970) Accothion and Aquatic Insects: Monitoring of Stream Populations. (Unpublished study received Mar 15, 1973 under 10308-2; prepared by Univ. of Maine, Dept. of Entomology, submitted by Sumitomo Chemical Co., Ltd., Baltimore, MD; CDL:004892-U)

00126919 Peterson, J. (1969) The Effects of Sumithion on Birds. (Unpublished study received Mar 15, 1973 under 10308-2; prepared by U.S. Fish and Wildlife Service, submitted by Sumitomo Chemical Co., Ltd., Baltimore, MD; CDL:004982-Y)

00126920 Peterson, J. (1970) The Effects of Accothion on Birds and Other Fauna. (Unpublished study received Mar 15, 1973 under 10308-2; prepared by U.S. Fish and Wildlife Service, submitted by Sumitomo Chemical Co., Ltd., Baltimore, MD; CDL:004892-Z)

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OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Fenitrothion Standard

MRID	CITATION
00126929	Fink, R.; Grimes, J. (1978) Simulated Field Study in Alfalfa with Bobwhite Quail, Mallard Ducks, and Rabbit Utilizing Sumithion 8E Wildlife International Ltd. Identification No. WI-546. Final rept. (Unpublished study received Feb 6, 1979 under 476-EX-80; prepared by Wildlife International Ltd., submitted by Stauffer Chemical Co., Richmond, CA; CDL:097792-A)
00126931	Johansen, C.; Atkins, E. (1978) Bee Toxicology: Sumithion 8EC: TEst No. I-59-P-78. (Unpublished study received Feb 6, 1979 under 476-EX-80; prepared by Washington State Univ., Dept. of Entomology and Univ. of California--Riverside, Dept. of Entomology, submitted by Stauffer Chemical Co., Richmond, CA; CDL: 097792-C)
00126947	Spillner, C., Neuberger, A. (1977) Sumithion Adsorption and Desorption in Various Soils: Project 149046. (Unpublished study received Aug 17, 1977 under 39398-3; submitted by Sumitomo Chemical America, Inc., New York, NY; CDL:231306-L)
00126956	Peterson, R.; Zitko, V. (1973) Variations in Stream Insect Drift Associated with Operational and Experimental Contamination with Fenitrothion in New Brunswick: Technical Report No. 439. (Unpublished study received Aug 17, 1977 under 39398-3; prepared by Canada, Fisheries Research Board, Biological Station, submitted by Sumitomo Chemical America, Inc., New York, NY; CDL:231306-U)
00126958	Rabeni, C.; Gibbs, K. (1976) The Effects of Sumithion on Non Target Stream Insects in Maine, 1975: Miscellaneous Report 176. (Unpublished study received Aug 17, 1977 under 39398-3; prepared by Univ. of Maine, Life Sciences and Agriculture Experiment Station, Dept. of Entomology, submitted by Sumitomo Chemical America, Inc. New York, NY; CDL:231306-W)
00128048	McCann, J. (1970) Accothion 8 EC: Bluegill: Test No. 306. (Unpublished study received Nov 7, 1970 under 241-EX-50; prepared by Pesticides Regulation Div., Animal Biology Laboratory, submitted by U.S. Environment Protection Agency, Beltsville, MD; CDL:129845-A)
00135034	Stauffer Chemical Co. (1976) The Results of Tests on the Amount and Nature of the Residue, and Analytical Methodology Using Sumithion. (Compilation; unpublished study received Dec 1, 1976 under 476-EX-80; CDL:096472-A)
00143017	Griggs, L.; Jefferson, N.; Blair, M.; et al. (1984) One Year Dietary Toxicity Study in Dogs: Amendment to the Final Report: 491-011. Unpublished study prepared by International Research and Development Corp. 320 p.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Fenitrothion Standard

MRID	CITATION
00150219	Taylor, R. (1980) Frozen Stability Studies on Sumithion, Sumioxion, Aminosumithion, and 3-methyl-4-nitrophenol in Tissues and Milk: T-10416. Unpublished study prepared by Harris Labs, Inc. 190 p.
00150220	Mihara, Y.; Okuno, Y.; Mikami, Y.; et al. (1979) Supplementary Metabolism Study of Fenitrothion in Female Goat: Final Report: HT-70-0101-3. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 16 p.
00150223	Taylor, R. (1980) Frozen Stability Studies on Sumithion Sumioxon and 3-Methyl-4-nitrophenol in Poultry Tissue and Eggs: Projects Nos. T-1149 & T-1150. Unpublished study prepared by Harris Labs., Inc. 135 p.
00150224	McKay, J. (1981) Letter sent to E.R. Butts dated Jan 28, 1981: Analytical data from Sumithion stored grain study: Project No. 149046. 9 p.
00159565	Beavers, J. (1979) One-generation Reproduction Study - Mallard Duck: Sumithion Technical: Final Report: Project No. 144-112. Unpublished study prepared by Wildlife International Ltd. 31 p.
00160000	Hudson, R.; Tucker, R.; Haegele, M. (1984) Handbook of toxicity of pesticides to wildlife: Second edition. US Fish and Wildlife Service: Resource Publication 153. 91 p.
00163432	Suzuki, H.; Miyamoto, J. (1983) Mutagenicity Tests of Sumithion with Nitro Reductase-defective Bacteria: HT-30-0259. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 13 p.
05001991	Stevenson, J.H. (1978) The acute toxicity of unformulated pesticides to worker honey bees (Apis mellifera). Plant Pathology 27(1):38-40.
40094602	Johnson, W.; Finley, M. (1980) Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates: Resource Publication 137. US Fish and Wildlife Service, Washington, D.C. 106 p.
40228401	Mayer, F. (1986) Acute Toxicity Handbook of Chemicals to Estuarine Organisms: EPA/600/X-86/231. Prepared by US EPA Environmental Research Laboratory, Gulf Breeze, Fl. 275 p.
40243801	Pearce, P.; Peakall, D. Erskine, A. (1976) Impact on forest birds of the 1975 spruce budworm spray operation in New Brunswick. Canadian Wildlife Service Progress Notes No. 62, March, 1976. 7 p.

APPENDIX V

FORMS APPENDICES

OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

Attach separate page with a list of the data requirements your company agrees to satisfy.

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

Attach list of data requirements

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________ Date ____________________

Guidance Document for ______________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ____________________

Registrant's Name and Address: ______________________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated ______________ concerning a requirement for submission of "generic" data on the active ingredient ________________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated ____________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ________________________ and their registration number(s) is/are ________________ .

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ____
(Signature)

Dated: ____________________ ____
(Typed)

EPA Form 8570-27

APPENDIX II

LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

SUMMARY-2

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

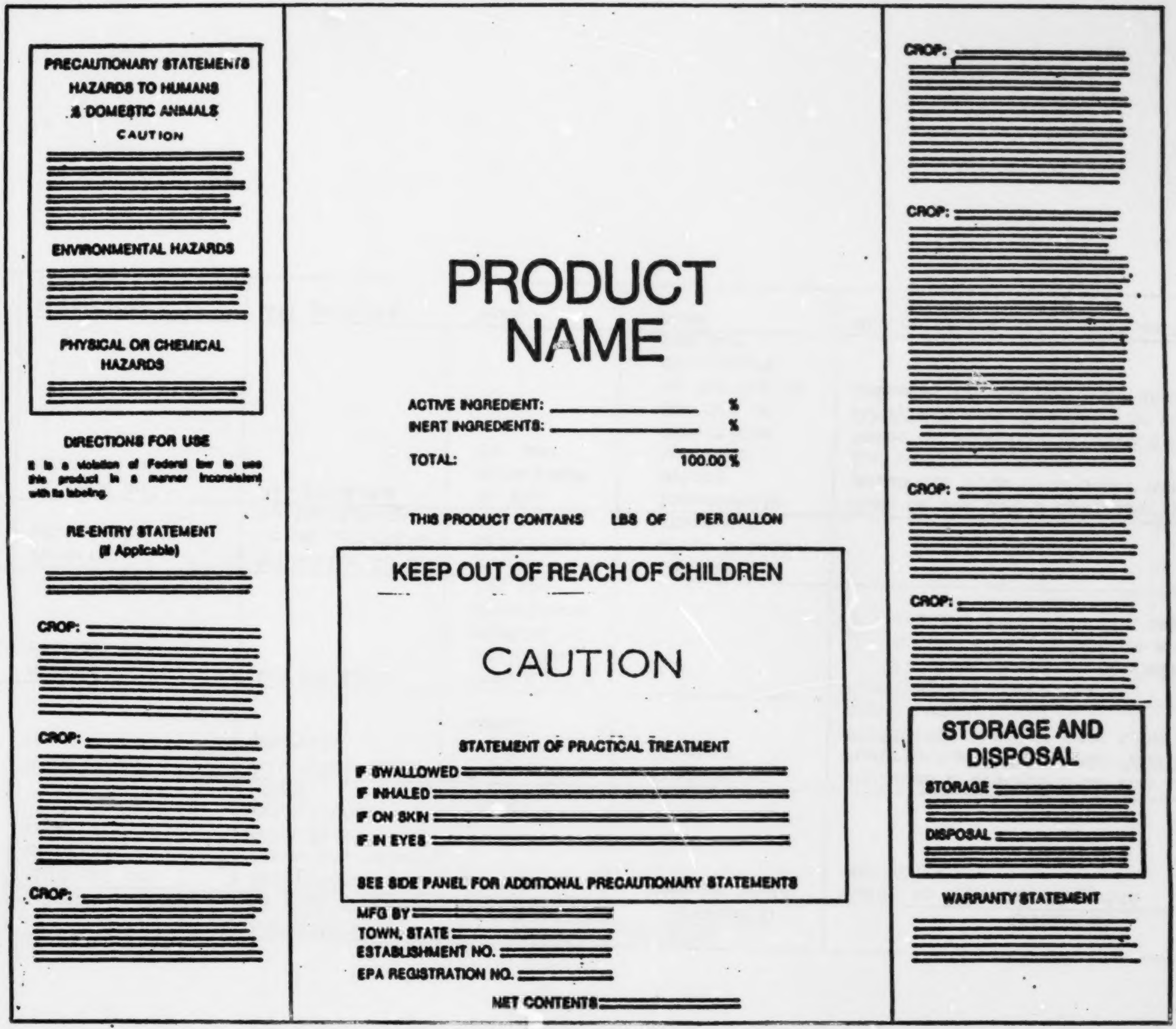
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
& DOMESTIC ANIMALS
CAUTION

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL
HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

CROP:

CROP:

CROP:

PRODUCT
NAME

ACTIVE INGREDIENT: ____ %
INERT INGREDIENTS: ____ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

CROP:

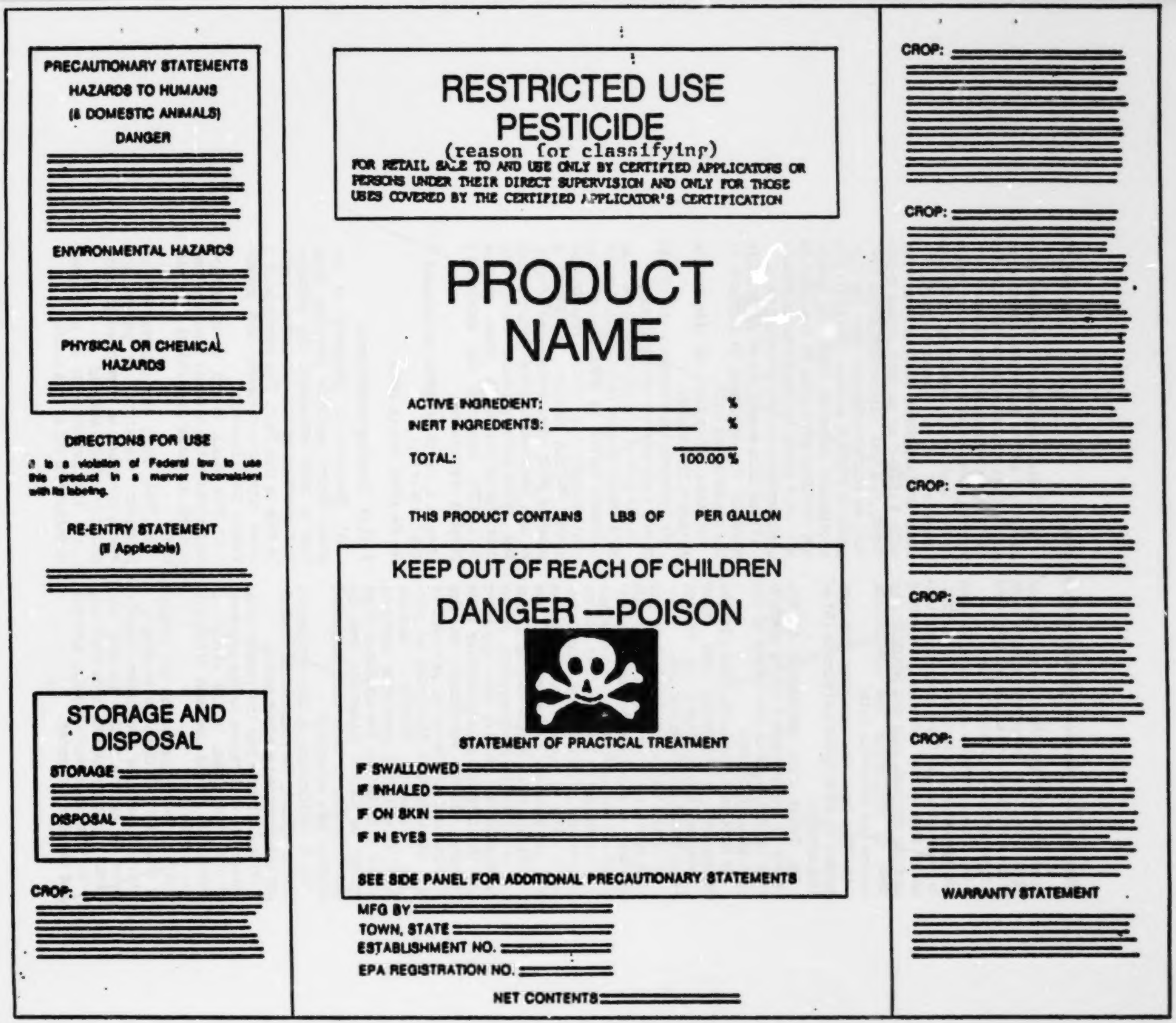
CROP:

STORAGE AND
DISPOSAL

STORAGE

DISPOSAL

WARRANTY STATEMENT



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

STORAGE AND DISPOSAL

STORAGE

DISPOSAL

CROP:

RESTRICTED USE PESTICIDE

(reason for classifying)

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

PRODUCT NAME

ACTIVE INGREDIENT: ________ %
INERT INGREDIENTS: ________ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

DANGER —POISON

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

~~cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).~~

~~(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:~~

~~(1) The data the applicant has submitted to EPA under paragraph (b) of this section;~~

~~(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and~~

~~(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.~~

~~(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:~~

~~(1) A notification of the applicant's intent to apply for registration, including the proposed product name;~~

~~(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);~~

~~(3) An identification of the item(s) of data to which the offer applies;~~

~~(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and~~

~~(5) The applicant's name, address and telephone number.~~

~~(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:~~

~~(1) All data submitted or specifically cited by the applicant in support of the registration; and~~

~~(2) Each other item of data in the Agency's files which:~~

~~(i) Concerns the properties or effects of any such active ingredient; and~~

~~(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.~~

~~(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)~~

~~[44 FR 27953, May 11, 1979]~~

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) *Name and address of producer, registrant, or person for whom produced.* An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run par-

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allel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requir ments concerning content, placemen type size, and prominence are give below.

(1) *Required front panel statement* With the exception of the chil hazard warning statement, the text r quired on the front panel of the lab is determined by the Toxicity Categ ry of the pesticide. The category is a signed on the basis of the highe hazard shown by any of the indicato in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD$_{50}$	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC$_{50}$	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2. thru 20 mg/liter.	Greater than 20 mg/li
Dermal LD$_{50}$	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation a 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitte except when the Agency determine that such labeling is necessary to pr vent unreasonable adverse effects o man or the environment. In no cas shall more than one human hazar signal word appear on the front pane of a label.

(ii) *Child hazard warning.* Every pe ticide product label shall bear on th front panel the statement "keep out o reach of children." Only in case where the likelihood of contact wit children during distribution, market ing, storage or use is demonstrated b the applicant to be extremely remot or if the nature of the pesticide is suc that it is approved for use on infant or small children, may the Administra tor waive this requirement.

(iii) *Statement of practical treat ment*—(A) *Toxicity Category I.* statement of practical treatment (fir aid or other) shall appear on the fron panel of the label of all pesticides fal ing into Toxicity Category I on th basis of oral, inhalation or dermal tox icity. The Agency may, however permit reasonable variations in th placement of the statement of pract cal treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Av[illegible]ntact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of

100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

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(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

~~§ 162.11 Criteria for determinations of unreasonable adverse effects.~~

~~(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing*—(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five (45) days from the date such notice is sent to submit evidence in rebuttal of the presumption; provided, however, that for good cause shown the Administrator may grant an additional sixty~~

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes (see list in this Appendix) or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes (see list in this Appendix) or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

PESTICIDE ACTIVE INGREDIENTS THAT ARE ACUTE HAZARDOUS WASTES

I. PESTICIDES ON THE "E" LIST (with RCRA # and CAS #) [40 CFR 261.33(e)]

Acrolein	P003	107-13-1
Aldicarb	P070	116-06-3
Aldrin	P004	309-00-2
Allyl alcohol	P005	107-18-6
Aluminum phosphide	P006	1302-45-0
4-Aminopyridine (Avitrol)	P008	504-24-5
Arsenic acid	P010	7778-39-4
Arsenic pentoxide	P011	1303-28-2
Arsenic trioxide	P012	1327-53-3
Calcium cyanide	P021	592-01-8
Carbon disulfide	P022	75-15-0
p-Chloroaniline	P024	106-47-8
Cyanides (soluble cyanide salts not otherwise specified)	P030	
Cyanogen chloride	P031	506-77-4
Dieldrin	P037	60-57-1
O,O-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate (disulfoton)	P039	298-04-4
O,O-Diethyl O-pyrazinyl phosphorothioate (Zinophos®)	P040	297-97-2
Dimethoate	P044	60-51-5
O,O-Dimethyl O-p-nitrophenyl phosphorothioate (methyl parathion)	P071	298-00-0
4,6-Dinitro-o-cresol and salts	P047	534-52-1
4,6-Dinitro-o-cyclohexylphenol	P034	131-89-5
Dinoseb	P020	88-85-7
Endosulfan	P050	115-29-7
Endothall	P088	129-67-9
Endrin	P051	72-20-8
Famphur	P097	52-85-7
Fluoroacetamide	P057	640-19-7
Heptachlor	P059	76-48-8
Hexachlorohexahydro-exo,exo-dimethanonaphthalene (Isodrin)	P069	465-73-6
Hydrocyanic acid	P063	74-90-8
Methomyl	P066	16752-77-5
alpha-Naphthylthiourea (ANTU)	P072	86-88-41
Nicotine and salts	P075	54-11-5
Octamethylpyrophosphoramide (OMPA, schradan)	P085	152-16-9
Parathion	P089	56-38-2
Phenylmercuric acetate (PMA)	P092	62-38-4
Phorate	P094	298-02-2
Potassium cyanide	P098	151-50-8
Propargyl alcohol	P102	107-19-7
Sodium azide	P105	26628-22-8
Sodium cyanide	P106	143-33-9
Sodium fluoroacetate	P058	62-74-8

Strychnine and salts	P108	57-24-9 60-41-3
O,O,O,O-Tetraethyl dithiopyrophosphate (sulfotepp)	P109	3689-24-5
Tetraethyl pyrophosphate	P111	107-49-3
Thallium sulfate	P115	7446-18-6
Thiofanox	P045	39196-18-4
Toxaphene	P123	8001-35-2
Warfarin (>0.3%)	P001	81-81-2
Zinc phosphide (>10%)	P122	1314-84-7

50 ACTIVES

II. PESTICIDES DERIVED FROM TRI-, TETRA-, AND PENTACHLOROPHENOLS [40 CFR 261.31]

2-Chloroethyl 2-(2,4,6-trichlorophenoxy) ethyl ether	F027	5324-22-1
Dehydroabietylammonium pentachlorophenoxide	F027	35109-57-0
Erbon	F027	136-25-4
O-ethyl O-(2,4,5-trichlorophenyl) ethylphosphonothioate	F027	327-98-0
2,2'-Methylenebis (3,4,6-trichlorophenol) (Hexachlorophene)	F027	70-30-4
--Potassium salt of	F027	67923-62-0
--Sodium salt of	F027	3247-34-5
--Disodium salt of	F027	5736-15-2
Pentachlorophenol	F027	87-86-5
--Potassium salt of	F027	7778-73-6
--Sodium salt of	F027	131-52-2
--Zinc salt of	F027	2917-32-0
--Zinc salt of N-alkyl (C_{16}-C_{18})-1,3-propanediamine	F027	
--Pentachlorophenyl laurate	F027	3772-94-9
Potassium trichlorophenate (2,4,6)	F027	2591-21-1
Potassium trichlorophenate (2,4,5)	F027	35471-43-3
Silvex	F027	93-72-1
--2-Butoxyethyl ester	F027	19398-13-1
--Butoxypolypropoxypropyl ester	F027	53404-07-2
--Butoxypropyl ester	F027	25537-26-2
--Diethanolamine salt	F027	51170-59-3
--Diisopropanolamine salt	F027	53404-09-4
--Dimethylamine salt	F027	55617-85-1
--Dipropylene glycol isobutyl ether ester	F027	53535-26-5
--Ethanolamine salt	F027	7374-47-2
--2-Ethylhexyl ester	F027	53404-76-5
--Isooctyl ester	F027	53404-14-1

--Isopropanolamine salt	F027	53404-13-0
--Monohydroxylaluminum salt	F027	69622-82-8
--Polypropoxypropyl ester	F027	83562-66-7
--Potassium salt	F027	2818-16-8
--Propylene glycol isobutyl ether ester	F027	53466-84-5
--Sodium salt	F027	37913-89-6
--Triethanolamine salt	F027	17369-89-0
--Triethylamine salt	F027	[illegible]404-74-3
--Triisopropanolamine salt	F027	53404-75-4
--Tripropylene glycol isobutyl ether ester	F027	53535-30-1
Sodium 2-(2,4,5-trichlorophenoxy) ethyl sulfate	F027	3570-61-4
Tetrachlorophenols	F027	25167-83-3
--Alkylamine*amine salt (as in fatty acids of coconut oil)	F027	
--Potassium salt	F027	53535-27-6
--Sodium salt	F027	25567-55-9
2,4,5-Trichlorophenol	F027	95-95-4
2,4,6-Trichlorophenol	F027	88-06-2
2,4,5-Trichlorophenol salt of 2,6-bis[(dimethylamino)methyl] cyclohexanone	F027	53404-83-4
2,4,5-Trichlorophenol, sodium salt	F027	136-32-3
2,4,6-Trichlorophenol, sodium salt	F027	3784-03-0
2,4,5-Trichlorophenoxyacetic acid	F027	93-79-8
--Alkyl C-12 amine salt	F027	53404-84-5
--Alkyl C-13 amine salt	F027	53404-85-6
--Alkyl C-14 amine salt	F027	53535-37-8
--N,N-diethylethanolamine salt	F027	53404-86-7
--Dimethylamine salt	F027	6369-97-7
--N,N-dimethyllinoleylamine salt	F027	53404-88-9
--N,N-dimethyloleylamine salt	F027	53404-89-0
--N-oleyl-1,3-propylene diamine salt	F027	53404-87-8
--Sodium salt	F027	13560-99-1
--Triethanolamine salt	F027	3813-14-7
--Triethylamine salt	F027	2008-46-0
--Alkyl (C3H7 - C7H9) ester	F027	
--Amyl ester	F027	120-39-8
--Butoxyethoxypropyl ester	F027	1928-58-1
--2-Butoxyethyl ester	F027	2545-59-7
--Butoxypropyl ester	F027	1928-48-9
--Butyl ester	F027	93-79-8
--Dipropylene glycol isobutyl ether ester	F027	53535-31-2
--2-Ethylhexyl ester	F027	1928-47-8
--Isobutyl ester	F027	4938-72-1

--Isopropyl ester	F027	93-78-7
--Propylene glycol isobutyl ether ester	F027	53466-86-7
--Tripropylene glycol isobutyl ether ester	F027	53535-32-3
4-(2,4,5-Trichlorophenoxy)butyric acid [2,4,5-TB]	F027	93-80-1
2-(2,4,5-Trichlorophenoxy)ethyl hydrogen sulfate [2,4,5-TES]	F027	69633-04-1
1,4',5'-Trichloro-2'-(2,4,5-trichlorophenoxy) methanesulfonanilide [Edolan U]	F027	69462-14-2

PESTICIDES THAT ARE TOXIC HAZARDOUS WASTES

PESTICIDES ON THE "F" LIST [40 CFR 261.33(f)] (with	RCRA #, and	CAS #
Acetone	U002	67-64-1
Acrylonitrile*	U009	107-13-1
Amitrole	U011	61-82-5
Benzene*	U019	71-43-2
Bis(2-ethylhexyl)phthalate	U028	117-81-7
Cacodylic acid	U136	75-60-5
Carbon tetrachloride*	U211	56-23-5
Chloral (hydrate) (chloroacetaldehyde)	U034	302-17-0
Chlordane, technical*	U036	57-74-9
Chlorobenzene*	U037	108-90-7
4-Chloro-m-cresol	U039	59-50-7
Chloroform*	U044	67-66-3
o-Chlorophenol	U048	95-57-8
Creosote	U051	8021-39-4
Cresylic acid (cresols)*	U052	1319-77-3
Cyclohexane	U056	110-82-7
Cyclohexanone	U057	108-94-1
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one (Kepone, chlordecone)	U142	143-50-0
1,2-Dibromo-3-chloropropane (DBCP)	U066	96-12-8
Dibutyl phthalate	U069	84-74-2
S-2,3-(Dichloroallyl diisopropyl-thiocarbamate) (diallate,Avadex)	U062	2303-16-4
o-Dichlorobenzene*	U070	95-50-1
p-Dichlorobenzene*	U072	106-46-7
Dichlorodifluoromethane (Freon 12®)	U075	75-71-8
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide, Kerb®)	U192	23950-58-5
Dichloro diphenyl dichloroethane (DDD)	U060	72-54-8
Dichloro diphenyl trichloroethane (DDT)	U061	50-29-3
Dichloroethyl ether	U025	1191-17-9
2,4-Dichlorophenoxyacetic, salts and esters (2,4-D)*	U240	94-75-7
1,2-Dichloropropane	U083	8003-19-8
1,3-Dichloropropene (Telone)	U084	542-75-6
Dimethyl phthalate	U102	131-11-3
Epichlorohydrin (1-chloro-2,3-epoxypropane)	U041	106-89-8
Ethyl acetate	U112	141-78-6
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)	U038	510-15-6

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*Proposed for deletion by TCLP proposal

Ethylene dibromide (EDB)	U067	106-93-4
Ethylene dichloride*	U077	107-06-2
Ethylene oxide	U115	75-21-8
Formaldehyde	U122	50-00-0
Furfural	U125	98-01-1
Hexachlorobenzene*	U127	118-74-1
Hexachlorocyclopentadiene	U130	77-47-4
Hexachloroethane*	U131	67-72-1
Hydrofluoric acid	U134	7664-39-3
Isobutyl alcohol*	U140	78-83-1
Lead acetate	U144	301-04-2
Lindane*	U129	58-89-9
Maleic hydrazide	U148	123-33-1
Mercury	U151	7439-97-6
Methoxychlor*	U247	72-43-5
Methyl alcohol (methanol)	U154	67-56-1
Methyl bromide	U029	74-83-9
Methyl chloride	U045	74-87-3
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene) [acute waste per 261.31]	U132	70-30-4
Methylene chloride*	U080	75-09-2
Methyl ethyl ketone*	U159	78-93-3
4-Methyl-2-pentanone (methyl isobutyl ketone)	U161	108-10-1
Naphthalene	U165	91-20-3
Nitrobenzene*	U169	98-95-3
p-Nitrophenol	U170	100-02-7
Pentachloroethane	U184	76-01-7
Pentachloronitrobenzene (PCNB)	U185	82-68-8
Pentachlorophenol* [acute waste per 261.31]	U242	87-86-5
Phenol*	U188	108-95-2
Pyridine*	U196	110-86-1
Resorcinol	U201	108-46-3
Safrole	U203	94-59-7
Selenium disulfide	U205	7488-56-4
Silvex [acute waste per 261.31]	U233	93-72-1
1,1,2,2-Tetrachloroethane*	U209	79-34-5
Tetrachloroethylene*	U210	127-18-4
2,3,4,6-Tetrachlorophenol* [acute waste per 261.31]	U212	
Thiram	U244	137-26-8
Toluene*	U220	108-88-3
1,1,1-Trichloroethane* (methyl chloroform)	U226	71-55-6
Trichloroethylene*	U228	79-01-6
Trichloromonofluoromethane (Freon 11®)	U121	75-69-4
2,4,5-Trichlorophenol* [acute waste per 261.31]	U230	95-95-4
2,4,6-Trichlorophenol* [acute waste per 261.31]	U231	88-06-2

2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)* [acute waste per 261.31]	U232	93-76-5
Warfarin (<0.3%)	U248	81-81-2
Xylene	U239	1330-20-7
Zinc phosphide (<10%)	U249	1314-84-7

83 ACTIVES

APPENDIX III

USE INDEX APPENDIX

EPA Compendium of Acceptable Uses

O,O-DIMETHYL O-(4-NITRO-M-TOLYL) PHOSPHOROTHIOATE

TABLE OF CONTENTS

Site Name	Page
TERRESTRIAL NONFOOD CROP	2
(Ornamental Plants and Forest Trees)	2
GREENHOUSE NONFOOD CROP	4
(Ornamental Plants and Forest Trees)	4
DOMESTIC OUTDOOR	5
(Household)	5
FORESTRY	6
(Ornamental Plants and Forest Trees)	6
INDOOR	8
(Animals and Their Man-made Premises)	8
(Household)	8
(Wide Area and General Indoor/Outdoor Treatment)	9
(Commercial and Industrial Uses)	10
Aircraft (Areas other than edible product areas)	10
Azalea	2
Birch	2
Boxwood	2
Buses (Areas other than edible product areas)	10
Coleus	2
Commercial, Industrial and Institutional Areas (Areas other than edible product areas)	10
Crape Myrtle	2
Domestic Dwelling (Outdoor)	5
Domestic Dwellings, Indoor	8
Domestic Dwellings, Indoor	9
Elm	2
Euonymus	2
Fir	2
Fir	6
Gardenia	2
Green Ash	2
Greenhouse Ornamentals	4
Hackberry	2
Hemlock	2
Holly	2
Iris	2
Japanese Andromeda	2
Juniper	2
Oak	2
Pet Premises	8
Pine	2
Pine	3
Pine	7
Poplar	2
Privet	2
Pyracantha	2
Railroad Cars (Areas other than edible product areas)	10
Rhododendron	2
Roses	2

EPA Compendium of Acceptable Uses

O,O-DIMETHYL O-(4-NITRO-M-TOLYL) PHOSPHOROTHIOATE

TABLE OF CONTENTS

Site Name	Page
Spruce	2
Spruce	6
Sweetgum	2
Taxus	2
Trailers (Areas other than edible product areas)	10
Trucks (Areas other than edible product areas)	10
Tuliptree	2
Vessels (Areas other than edible product areas)	10
Willow	2

c105901 O,O-DIMETHYL O-(4-NITRO-M-TOLYL) PHOSPHOROTHIOATE*

TYPE PESTICIDE: Insecticide, Acaricide

FORMULATIONS:

Tech	(95%)
FI	(25.02%, 80%)
WP	(40%)
EC	(4 lb/gal, 8 lb/gal)
SC/L	(93%)

GENERAL WARNINGS AND LIMITATIONS: The use of the following formulations is limited to professional applicators: WP (40%), EC (4 lb/gal, 8 lb/ gal), SC/L (93%). When mixing, loading, spraying or cleaning equipment used to apply fenitrothion, wear chemical resistant gloves, protective suits or coveralls that cover the arms, legs, and torso, and chemical resistant shoes, boots, or shoe covers. Aircraft operators: Pilots can wear long-sleeved shirt and long pants but must have a clean pair of chemical resistant gloves available for exiting the aircraft.

BEE CAUTION: Fenitrothion is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply fenitrothion or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

Agricultural Crop Tolerances (other than those listed in the text):

Wheat, gluten (postharvest in Australia)	15 ppm

*Fenitrothion
Sumithion

EPA Compendium of Acceptable Uses

O,O-DIMETHYL O-(4-NITRO-M-TOLYL) PHOSPHOROTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	TERRESTRIAL NONFOOD CROP		
	(Ornamental Plants and Forest Trees)		
/34022AA	Azalea		
/35028AA	Birch		Reentry into treated areas is prohibited for 24 hours after the end of the application, unless the protective clothing is worn. When mixing, loading, spraying or cleaning equipment, or during early reentry into treated areas, wear chemical resistant gloves, protective suits or coveralls that cover the arms, legs, and torso, and chemical resistant shoes, boots, or shoe covers.
/34031AA	Boxwood		
/31071AA	Coleus		
/34046AA	Crape Myrtle		
/35049AA	Elm		
/34053AA	Euonymus		
/35051AA	Fir		
/34063AA	Gardenia		
/35065AA	Green Ash		
/35067AA	Hackberry		
/35068AA	Hemlock		
/34070AA	Holly		
/31126AA	Iris		
/34078AA	Japanese Andromeda		
/35073AA	Juniper		
/35093AA	Oak		
/35098AA	Pine		
/35101AA	Poplar		
/34088AA	Privet		
/34058AA	Pyracantha		
/34118AA	Rhododendron		
/34120AA	Roses		
/35116AA	Spruce		
/35118AA	Sweetgum		
/35130AA	Taxus		
/35120AA	Tuliptree		
/35128AA	Willow		
/32000CA			
IQAXARA	Andromeda lace bug	0.5-1 lb/100 gal (8 lb/gal EC)	Foliar application. Apply as a broadcast or spot spray to the point of runoff. Repeat at 7 day intervals as needed.
ITAPAGA	Azalea leafminer		
IOAHAKA	Balsam gall midge		
ISBEAMA	Birch leafminer		
INASCSA	Black vine weevil		
IRAXAFA	Blistergall psyllid (Hackberry psyllid)		

Site and Pest | Dosages and Formulation(s) | Tolerance, Use, Limitations

Azalea cluster (continued)

Pest list continued from previous page.

IRAXAIA	Boxwood psyllid
IRAWAJA	Citrus mealybug
IRABAGA	Citrus whitefly
IRAHBEG	Cottony taxus scale (crawlers)
IRACDTA	Crapemyrtle aphid
INAMDAA	Elm leaf beetle
ILAVCKA	Eotetranychus spider mites
ISACAMA	European pine sawfly
ISADACA	European spruce sawfly (pine sawfly)
ITANACA	Fall cankerworm
ITABAIA	Fall webworm
ITAUAGA	Forest tent caterpillar
IQAXAFA	Hawthorn lace bug
INAMCVA	Imported willow leaf beetle
ITBCBVA	Iris borer
IRACAPA	Ivy aphid
IRAEAKA	Meadow spittlebug
INASCYA	Northern pine weevil
INASBRA	Pales weevil
ITAMAFA	Palmerworm
IRARAFG	Redpine scale (crawlers)
IRACCKA	Rose aphid
ISBEAIA	Roseslug
IRAEACA	Saratoga spittlebug
ILAVAMA	Southern red mite
ITBUASA	Spruce budworm
IRACCJA	Tuliptree aphid

EPA Compendium of Acceptable Uses

O,O-DIMETHYL O-(4-NITRO-M-TOLYL) PHOSPHOROTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/35098AA	Pine		Do not use this chemical in Bastrop and Burleson couties, TX without first consulting with endangered species personnel of Texas Parks and Wildlife or the U.S. Fish and Wildlife Service (telephone 817-334-2961) to ensure adequate safeguards for the endangered Houston toad. Do not use within 1/2 mile of known rec-cockaded woodpecker colonies. Apply spray to individual trees using hand or power operated ground application equipment.
INBQAOA	Southern pine beetle	1% finished spray (8 lb/gal EC)	Bark Application, Preventive Treatment. Apply thoroughly to the point of runoff. Apply from the ground level to the first limbs in early spring or anytime trees are threatened by infestation from nearby infested trees. Repeat at 90 day intervals during summer and early fall or as long as threat of attack exists.
		1% finished spray (8 lb/gal EC)	Bark Application, Remedial Treatment. Apply to the point of runoff. Apply to infested portions of trees or all sides of logs and limbs cut from infested trees. Make application after beetle attack has occurred but prior to beetle emergence.

GREENHOUSE NONFOOD CROP

(Ornamental Plants and Forest Trees)

/32000CA Greenhouse Ornamentals

Refer to TERRESTRIAL NONFOOD CROP, (Ornamental Plants and Forest Trees), Azalea cluster, for pests and use limitations.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	DOMESTIC OUTDOOR		
	(Household)		
/630030A	Domestic Dwelling (Outdoor)		
IOAAAAA IOAMAAA	Flies Mosquitoes	1% finished spray (4 lb/gal EC)	Outdoor application. Spray outside surfaces of windows and door frames, and other areas where these pests may enter the home. Also, spray dark corners and localized resting areas (such as under eaves) or porches, patios and garages where these pests may congregate. Repeat as necessary. Dilute with water or deodorized kerosene (or equivalent grade oil).
ISASAAA	Ants	1% finished spray (4 lb/gal EC)	Outdoor treatment. Spray trails, nests and points of entry. Spray on ants where possible. Repeat as necessary.

EPA Compendium of Acceptable Uses

O,O-DIMETHYL O-(4-NITRO-M-TOLYL) PHOSPHOROTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	FORESTRY		
	(Ornamental Plants and Forest Trees)		
/30043AA /30064AA	Fir Spruce		RESTRICTED USE PESTICIDE. This pesticide is toxic to wildlife and extremely toxic to aquatic invertebrates. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes) except under the forest canopy. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes. Use limited to the northeastern United States. Apply under the supervision of qualified personnel responsible for pest control programs and after a careful pest population forecast is made on the infested forest area. Apply at the peak of fourth instar larval development. Mix in sufficient water or solvent so as to apply 10 to 20 ounces of finished spray per acre by aircraft.
ITBUASC	Spruce budworm (3-4th instar)	0.125-0.188 lb/A (8 lb/gal EC) (93% SC/L)	Foliar application. Make 2 applications 4 to 6 days apart.
ITBUASC	Spruce budworm (4-5th instar)	1 application 0.188 lb/A or 2 applications 0.125-0.188 lb/A (8 lb/gal EC) (93% SC/L)3	Foliar application. When making 2 applications allow 4 to 6 days between treatments.

O,O-DIMETHYL O-(4-NITRO-M-TOLYL) PHOSPHOROTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/30059AA	Pine		Apply spray to individual trees using hand or power operated ground application equipment.
INBQAOA	Southern pine beetle	2% finished spray (8 lb/gal EC)	Bark Application, Preventive Treatment. Apply thoroughly to the point of runoff. Apply from the ground level to the first limbs in early spring or anytime trees are threatened by infestation from nearby in infested trees. Repeat at 90 day intervals during summer and early fall or as long as threat of attack exists.
		1% finished spray (8 lb/gal EC)	Bark Application, Remedial Treatment. Apply to the point of runoff. Apply to infested portions of trees or all sides of logs and limbs cut from infested trees. Make application after beetle attack has occurred but prior to beetle emergence.
		[SLN] 2 ml of 8 lb/gal per inch of tree diameter at breast height (8 lb/gal EC)	SLN - Use limited to LA and MS. Hack and squirt injection. Apply undiluted. For the hack and squirt technique use a handheld hatchet to make cuts 2 to 3 inches apart around the trunk of the tree. The height of the cuts is whatever is comfortable for the person doing the work. Apply fenitrothion delivering 1 milliliter per squirt. Treat all trees that have green needles in the crown. Treat all trees in the buffer zone 2 times the height of the trees that are being injected all the way around the infested area. Note: the total number of squirts per tree should be divided equally among the cuts around the tree trunk.

Site and Pest — **Dosages and Formulation(s)** — **Tolerance, Use, Limitations**

INDOOR

General Warnings and Limitations: When used in dwellings, avoid deposits which could be frequently contacted by children. Do not permit children or pets in treated areas until surfaces are dry. Do not use in kitchens or food serving areas while food is exposed. Solvents used in emulsifiable concentrate formulations may stain certain plastic, rubber, and asphalt materials such as tiles and floor coverings. Do not apply to carpets due to possibility of staining. Avoid spotting of wallpaper and fabrics. Emulsifiable concentrates may be diluted with oil.

(Animals and Their Man-made Premises)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/54000JA	Pet Premises		
ILAMAZA	Brown dog tick	1% finished spray (4, 8 lb/gal EC)	Enclosed premises treatment. Spot treat infested areas such as pet beds and resting quarters, nearby cracks and crevices, along and behind baseboards, window and door frames and localized areas of floor coverings. Old bedding of pets should be removed and replaced with clean fresh bedding after treatment.
IMNAAAA	Fleas		

(Household)

/63001OA /70001JC /70002JC /77000JC /70005JC /70006JC /70034JC	Domestic Dwellings, Indoor		
ISASAAA	Ants	1% finished spray (4, 8 lb/gal EC)	Indoor treatment. Apply as a coarse spot spray or apply with a paint brush to baseboards, storage areas, around water pipes, behind and under refrigerators, cabinets, sinks and stoves, underside of pallets and similar areas where pests may hide or enter. Inspect treated area 14 to 28 days after initial application.
ILAMAZA	Brown dog tick		
ISBAAAA	Centipedes		
INABADA	Cigarette beetle		
IVAAABA	Cockroaches		
INBUATA	Confused flour beetle		
IVAHAAA	Crickets		
IMDAAAA	Earwigs		
IMPBABA	Firebrats		
IMNAAAA	Fleas		
ILABABA	Grain mite		
IJCAAAA	Millipedes		

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Domestic Dwellings, Indoor (continued)		
	Pest list continued from previous page.		
IJEBAAA	Scorpions		
IMPBACA	Silverfish		
ISFAAEA	Sowbugs		
IKAAAAA	Spiders		
IKADAAA	Tarantulas		
	(Wide Area and General Indoor/Outdoor Treatment)		
/63005CA	Domestic Dwellings, Indoor		
			Do not make more than 1 application every 3 months. Do not apply in food areas.
IDAMAJJ	Anopheles mosquitoes (adults)	40 ml of 5% finished spray sq.m or 1 kilogram/8 liters/200 sq.m [2 gm/sq.m] (40% WP)	For use only by or under the supervision of state or federal officials responsible for malaria control. Apply residual spray to wall surfaces. Remove occupants, pets, birds, and cover fish aquariums before application. Food should be removed and food handling equipment covered during application and or washed after application is complete. No food handling or preparation areas are to be sprayed. The floor must be covered before application and the covering disposed of in accordance with disposal procedures specified on labeling. After application do not reoccupy until spray deposits have dried. Do not make more than 1 application every 3 months. Before reoccupying, open all doors and windows and ventilate thoroughly.

O,O-DIMETHYL O-(4-NITRO-M-TOLYL) PHOSPHOROTHIOATE

(Commercial and Industrial Uses)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/70001JC	Aircraft (Areas other than edible product areas)		
/70002JC	Buses (Areas other than edible product areas)		
/77000JC	Commercial, Industrial and Institutional Areas (Areas other than edible product areas)		
/70005JC	Railroad Cars (Areas other than edible product areas)		
/70006JC	Trailers (Areas other than edible product areas)		
/70006JC	Trucks (Areas other than edible product areas)		
/70034JC	Vessels (Areas other than edible product areas)		

Refer to INDOOR, (Household), Domestic Dwellings, Indoor, for pest and use information.

O,O-DIMETHYL O-(4-NITRO-M-TOLYL) PHOSPHOROTHIOATE

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

AERIAL, MOTHPROOFING AND TANK MIX APPLICATIONS

9001500
AAAAAAA Aerial Application

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
--	Refer to FORESTRY (Ornamental Plants and Forest Trees) Fir, Spruce	

125

EPA Compendium of Acceptable Uses

O,O-DIMETHYL O-(4-NITRO-M-TOLYL) PHOSPHOROTHIOATE

Listing of Registered Pesticide Products by Formulation

&095.0001 95% technical chemical
O,O-dimethyl O-(4-nitro-m-tolyl) phosphorothioate (105901)
039398-00004

&025.0202 25.02% formulation intermediate
O,O-dimethyl O-(4-nitro-m-tolyl) phosphorothioate (105901), d-cis/trans allethrin (004005), heavy aromatic naphtha (006602) plus N-octyl bicycloheptenedicarboximide (057001)
039398-00024

&080.0002 80% formulation intermediate
O,O-dimethyl O-(4-nitro-m-tolyl) phosphorothioate (105901) plus aromatic petroleum distillate (006601)
039398-00023

&040.0007 40% wettable powder
O,O-dimethyl O-(4-nitro-m-tolyl) phosphorothioate (105901)
039398-00009

&104.0012 4 lb/gal emulsifiable concentrate
O,O-dimethyl O-(4-nitro-m-tolyl) phosphorothioate (105901) plus aromatic petroleum distillate (006601)
039398-00022

O,O-dimethyl O-(4-nitro-m-tolyl) phosphorothioate (105901) plus xylene range aromatic solvent (086803)
000655-00751

&108.0012 8 lb/gal emulsifiable concentrate
O,O-dimethyl O-(4-nitro-m-tolyl) phosphorothioate (105901)
039398-00003

O,O-dimethyl O-(4-nitro-m-tolyl) phosphorothioate (105901) plus xylene range aromatic solvent (086803)
000655-00740 004816-00667 039398-00012 039398-00013
039398-00015

(039398-00015) LA860008 MS860007

&293.0015 93% soluble concentrate/liquid
O,O-dimethyl O-(4-nitro-m-tolyl) phosphorothioate (105901)
039398-00007 039398-00011

O,O-DIMETHYL O-(4-NITRO-M-TOLYL) PHOSPHOROTHIOATE

Appendix A-1

Listing of Active Ingredient(s) Found in Combination with the Report Chemical

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
006501	aromatic petroleum derivative solvent	--
006601	aromatic petroleum distillate	--
004005	d-cis/trans allethrin	--
006602	heavy aromatic naphtha	--
057001	MGK 264	N-octyl bicycloheptenedicarboximide
086803	xylene range aromatic solvent	--

-- Use Common Name